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Promoting Compliance with Inhaler Use in Asthma Patients

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Candidate Thesis Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree MSc by Research, is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

Signed Elaine Mac Hale

RCSI Student Number: **08498091**

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Abstract

Introduction: Asthma is a chronic airways disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person. Symptoms may occur several times a day or week in affected individuals, and for some people symptoms become worse during physical activity or at night. Intermittent relapse from periods of stable asthma is the usual clinical course for most adults.
Incorrect inhaler usage is a significant problem in asthma management, resulting in poor control of asthma symptoms. The ability of patients to correctly use their inhaler might be directly linked to inhaler technique education. Education may result in better inhalation technique, improved compliance and asthma control. The economic burden of asthma is very substantial and is one of the highest among chronic diseases.

Research question: "What is the impact of a nurse-led education programme in promoting compliance with inhaler use in patients with Asthma?"

Methodology: This is a quantitative study engaging a quasi-experimental pre-test and post-test design, but with a follow-up period added. A cohort of 21 patients who met the inclusion criteria were recruited from the Out-Patient Department over a period of six months. During each visit, participants were asked to demonstrate how they took their inhaler. Any errors in technique were identified and rectified. Their demonstration was measured through observation and with the use of an Inhaler Proficiency Schedule (IPS). The participants were also asked a series of specific questions in relation to their condition, confidence level with self-administration of their inhaler, and adherence to prescribed frequency of use.

Results: The findings in this study show that inhaler education improves technique, promotes compliance and increases participant confidence levels in taking an inhaler, and as a result asthma symptoms improve. It also emerged that participants believed they were taking their inhaler correctly and so assumed that education drives were not targeted at them.

Implications: There were implications of the findings on the role and function of nurses, patients, pharmacists and the Health Service.

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Chapter 1 - Introduction and Background to the Study

Asthma is a chronic airways disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person (World Health Organisation (W.H.O.), 2010).

Atopic diseases such as asthma are increasing at a remarkable rate on a global scale. It is estimated that asthma affects 300 million people worldwide. Approximately 470,000 of these sufferers are in Ireland; this ranks Ireland as the country with the fourth highest prevalence per head of population in the world (Asthma Insights and Reality in Europe (AIRI), 2005). This imposes a considerable burden on the Irish Health Service and society. In 2003, the economic burden of asthma in Ireland to the state was €463 million and emergency care and hospitalisation accounted for €227 million (49%) of this. In adults, almost 12 working days a year are lost to asthma. This figure does not include the parents who miss work to care for children with asthma (Asthma Society of Ireland 2010).

The INHALE Report (2008) notes that, in Ireland, respiratory disease is the most common reason for people to visit their G.P. The Asthma Society (2007) report that approximately 25,000 A/E visits per annum are asthma-related and there are 6,000 to 7,000 asthma-related admissions to Irish hospitals every year. Therefore, increased resources to better manage the disease are required if this trend is to be reversed (INHALE, 2008).

The preferred delivery of medication treatment in asthma is via an inhaler because the medication reaches the target organ. There is also the advantage that less medication is required compared to oral methods, which in turn reduces the systemic side effects (Lavorini *et al.*2008; Burns, 2009). Correct inhalation technique alongside appropriate drug therapy is vital in effective asthma therapy. Incorrect inhaler usage is a significant problem in asthma management, as therapeutic effect may be diminished, resulting in poor control of asthma

symptoms. Patients may receive treatment, but without proper education and training in inhaler technique, the therapeutic benefit is below optimal (Lavorini *et al.* 2008).

The aim of the nursing profession is to deliver a high quality service, based on reliable and valid research. At its core, nursing research is guided by a caring ethos, but it is also concerned with the quality of its research which has a direct impact on the quality of care (Kelly and Long, 2000). The delivery of nursing care by safe autonomous and accountable practitioners is advocated by An Bord Altranais (2000) and places individual accountability with the nurse to develop and maintain the competence necessary for professional practice.

Nurses must be aware that they are accountable for their nursing practice and for working within their scope of practice (An Bord Altranais, 2000) and so nurses involved in educating patients must acquire the competencies and skills of an educator.

Health promotion and primary prevention of disease by nurses has evolved into an essential and critical aspect of their role and is practised across many therapeutic areas (Benson and Latter, 1998; Cutler 1999). The writer is employed as a research nurse in a dedicated research facility within an academic institution. The research facility is based on the campus of a large teaching hospital in Dublin, to which the academic institution is affiliated. The concept for this study came about as a result of the involvement of the writer in the development and running of an academic trial involving asthmatic patients. During the course of this trial, patients often demonstrated poor inhaler technique, and the writer realised that this was an area in which she could potentially improve patient care.

The research question to test this hypothesis was developed as follows:

"What is the impact of a nurse led education programme in promoting compliance with inhaler use in patients with Asthma?"

The aim in conducting this study was to examine the impact of a nursing education intervention on promoting compliance of patients with asthma in using an inhaler, and to consider the implications of the findings for the role and function of nurses in educating patients.

The objectives in this study can be summarised as follows:

- To describe current practices and asthma patient behaviour in using inhalers
- To identify deficiencies in the use of inhalers by asthma patients
- To develop and implement an asthma inhaler education programme for asthma patients
- To evaluate the impact of the asthma inhaler education programme
- To make recommendations on best practice in the use of inhalers by patients with asthma

Twenty one asthmatic patients participating in the medically focused study who corresponded with the inclusion \ exclusion criteria for the writer's research were enrolled in the study. The design included three identifiable stages: a pre-test stage, an intervention stage, and a post-test stage.

Pre-test Stage:
During this stage and following the collection of patient demographic data, each participant was asked to demonstrate their inhaler technique. Any errors in technique were identified and rectified.

Their demonstration was measured through observation and via the use of an Inhaler Proficiency Schedule (IPS). The participant was then asked a series of

specific questions in relation to their condition, confidence level with self-administration of their inhaler, and adherence to prescribed frequency of use.

Intervention Stage:

The participants had four visits over three months and were educated on using their inhaler.

Post-test Stage 1:

At visit 2 (which took place three months after entering the study), the pre-test demonstration of technique process was repeated.

Post-test Stage 2:

At the follow-up visit, which took place three months after visit 2, the pre-test demonstration of technique process was completed for a final time. Results show that the inability of participants to correctly use their inhaler may be as a direct result of poor inhaler technique education. Education results in better inhalation technique, which should lead to better asthma outcomes, but this education, must be repeated regularly.

The research identified that:

- some technique steps are harder to perform than others
- some technique steps are easier to perform than others
- poor performance of technique steps can be improved through education
- lapses in performance of specific steps occur
- participant confidence levels increased
- adherence and compliance improved
- peak flow readings improved for the new to DISKUS group from month 0
- peak flow readings improved for the already prescribed DISKUS group from month 3.

This dissertation is presented in six chapters.

- Chapter one provides an introduction to the study. The background to the concept for the study is presented and its significance is identified. The chapter outlines the background to the study and states the aims and objectives of the study.

- Chapter two presents a review of the literature on the topic. It includes a review of the role of the nurse in asthma care and the role of the nurse in health promotion is reviewed.

- Chapter three describes the process by which the writer conducted the study. This includes details on the research design, data collection methods, data analysis and ethical considerations.

- Chapter four presents the study findings. This includes an extensive analysis of the participants' technique and confidence in taking their inhaler.

- Chapter five discusses the study findings. The findings are compared with existing knowledge.

- Chapter six concludes the study incorporating the limitations and strengths of the study, implications of the study findings for nursing practice and education and also for pharmacists, patients and the potential for health service costs are considered. It also gives the writer's recommendations for future research.

Chapter 2 Literature Review

2.0 Introduction

This chapter outlines the literature review undertaken to ascertain the background knowledge of asthma, asthma management and the impact of nurse education on promoting inhaler use in patients with asthma.

A detailed literature review was undertaken to examine the current body of research and knowledge on:

- asthma,
- asthma management and education, and
- inhaler technique education.

Polit and Hungler (1997) have highlighted that a literature review is a key step in the research process. It helps to ensure that the research being undertaken will take account of existing knowledge. It therefore brings focus to the proposed research, and contributes to the elimination of duplicated effort. In the particular context of nursing and nursing education, a literature review helps educators to develop a sound knowledge base of other professions and disciplines (Cohen *et al.* 2003). The main function of a literature review is to develop the foundation of a sound study (LoBiondo-Wood and Haber. 2006).

Asthma is a chronic airways disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person (World Health Organisation (W.H.O.), 2010). Atopic diseases such as asthma are increasing at a remarkable rate on a global scale. It is estimated that asthma affects 300 million people worldwide. Between 17 million and 26 million Americans have asthma, and the number seems to be increasing. To put this in perspective, as recently as 1992, the number of Americans with asthma was

estimated at about 10 million, and this had risen 42% from 1982. Not only is asthma becoming more frequent, but it is also becoming more severe, despite modern drug treatments. Asthma accounts for almost 0.5 million hospitalisations, two million emergency department visits, and 5,000 deaths in the United States each year (http://medical-dictionary.thefreedictionary.com/asthma accessed online 2010).

Asthma is endemic in Ireland with approximately 470,000 sufferers; this ranks Ireland as the country with the fourth highest prevalence per head of population in the world (Asthma Insights and Reality in Europe (AIRI), 2005). This number is 3 times what it was just 30 years ago, and at least 20% of these patients have symptoms which are not controlled. The scale of the disease in Ireland has huge implications for our Health Service, both in terms of demand on services and running costs. The general cost impact is confirmed by Van Ganse *et al.* (2002), who report that patients with inadequately controlled asthma are more at risk of associated morbidity and mortality, with which comes a greater use of medical resources and thus a greater cost.

Asthma and other atopic conditions affect a substantial population of patients and impose a burden in terms of treatment cost, productivity loss and reduced quality of life. The severity of asthma can be classified by using the GINA guidelines (2002). Current advice is that asthma be managed by control rather than severity, i.e. look at the uncontrolled asthmatic and devise an action plan to support control (GINA updated guidelines 2009).

Diseases such as asthma and allergic rhinitis also have a significant societal impact. An Irish extension of the (AIRE) study, found that more than half of Irish people with asthma are awakened at night by asthma symptoms, and nearly three-quarters of sufferers experience some limitation in their normal activities due to asthma. Worryingly, almost eight in 10 children with asthma did not have their illness under control (AIRI 2005).

The literature review will explore the following topics:

- the Irish Health System,
- the role of the Nursing Profession,
- economic burden of asthma,
- defining asthma,
- disease severity,
- incidence,
- diagnosing asthma,
- management of asthma,
- asthma control,
- treatment options,
- patient compliance/adherence,
- patient and health professionals education,
- inhaler technique.

Finally the review will discuss the methodological issues that arose from the literature.

2.1 Search Strategy

A literature search was conducted using a selection of key words including asthma, asthma control, asthma management, quality of life, compliance/adherence, nursing intervention, nursing education, patient education. The databases used in the literature search included CINALH (Cumulative Index to Nursing and Allied Health) 1983-2010; Medline (Index Medicus online) 1983 to 2010; Pubmed and the Cochrane library. To support the literature review print indexes such as books, journals, publications of professional organisations and government documents were used. Websites for the National Asthma Societies of Ireland and the UK were also accessed. The only limit applied to the search was to select articles written in English.

2.2 The Irish Health System

In recent years the Irish Health Service has undergone considerable change and reorganisation. Annual expenditure has increased from €3.7 Billion in 1997 to €14.4 Billion in 2008 (Health Service Executive, (HSE) 2009). The Health Service Executive was established in 2005 as the single body with statutory responsibility for the management and delivery of health and personal social services in the Republic of Ireland. The launching by the HSE of the Transformation programme 2007-2010 signalled the start of a new era in Irish health care (HSE, 2006). The vision for the Health Service for 2010 is that everybody will have easy access to high quality care and services that they have confidence in and that staff are proud to provide (HSE, 2006).

In 2008 the Department of Health and Children (DoHC) published a policy framework for the management of chronic diseases. The report recognises that chronic diseases are a major health challenge, and that within the healthcare system, they represent the major component of service activity and expenditure. Given the projections which predict a doubling of the elderly population over the next 30 years, this will give rise to a significant increase in chronic diseases with the consequent burden on society, the healthcare system and individuals. In broad terms, the aims of the policy framework are:

- to promote and to improve the health of the population and reduce the risk factors that contribute to the development of chronic diseases, and
- to promote structured and integrated care in the appropriate setting that improves outcomes and quality of life for patients with chronic conditions.

The policy recommends that current and future initiatives on chronic disease should be patient centred; that the care should be structured and integrated in the appropriate setting that improves outcomes and quality of life for patients; and that there should be a greater emphasis on prevention.

The policy proposes that much of the treatment of patients with chronic disease can and should take place within the primary care setting. However it is also expected that with the appropriate level of support, unnecessary hospital admissions can be avoided and at the same time the quality of life of these patients can be improved. The policy confirms that programs to support self-care will need to be developed, as these will be key to managing these conditions successfully (DoHC, 2008).

2.3 The Economic Burden of Asthma

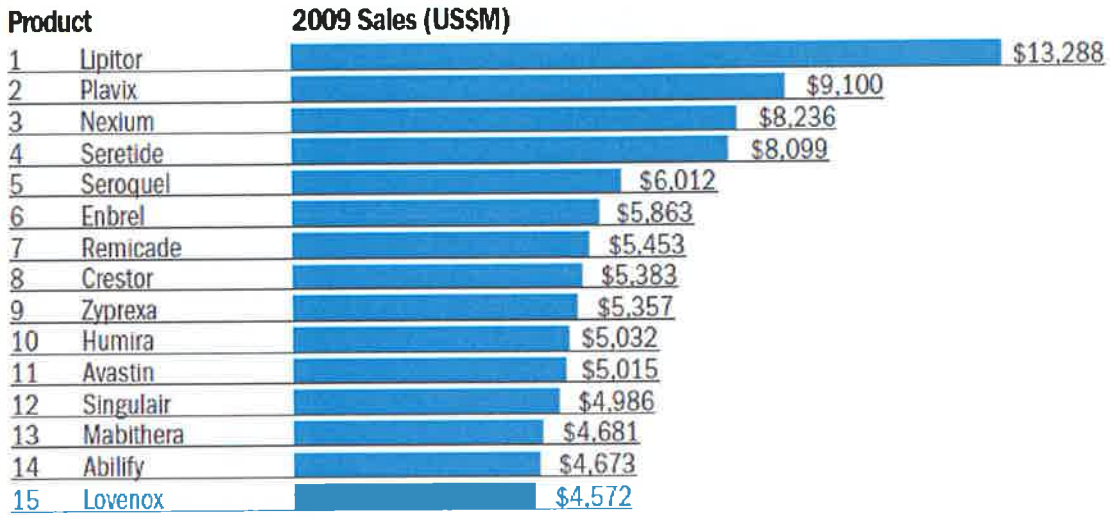
The economic burden of Asthma is very substantial and is one of the highest among chronic diseases. In Europe the cost is €17.7 billion per year (Asthma Society, 2010). Patients with chronic conditions are heavy users of the health services and it is estimated that three quarters of health expenditure is on the management of chronic conditions (tackling chronic conditions). Fink (2005) in discussing inhaler usage and associated problems has noted that out of an estimated 25 billion dollars spent for inhalers annually in the United States of America, approximately 5-7 billion dollars is wasted because of inhaler misuse.

Table 1 below shows that the amount of money spent on Asthma and COPD-related drugs globally is enormous. In 2009, Respiratory Agents were the third largest generator of revenue for the Pharmaceutical industry (Clinton and Mozeson, 2010).

Table 1. 2009 Sales of human prescription drugs by Therapeutic Class

Table 2 summarises the 2009 top 15 human prescription drugs by revenue generated. Fourth on the list is an asthma medication that is delivered via the DISKUS inhaler.

Table 2. 2009 Top 15 human prescription drugs by revenue generated



By 2015, sales of respiratory medicines are being forecast to grow by between 24% and 40% from 2009 levels (IMS Institute for Healthcare Informatics 2011).

In a systematic review of the literature conducted by Bahadori (2009), it was seen that hospitalization and medications are the largest cause of direct costs and that work and school absenteeism accounted for the majority of indirect costs. This burden includes the cost on the individual and on society, through direct and indirect costs. Direct costs include in- and out-patient care, diagnostic tests, nursing services, education, and medication. Indirect costs include work and school absenteeism, loss of productivity, travelling and waiting time for medical consultations, and most importantly, reduced participation in family life (Stock *et al.* 2005; Bateman *et al.* 2008).

In 2003, the economic burden of asthma in Ireland to the state was €463 million and emergency care and hospitalisation accounted for €227 million (49%) of this.

In adults, almost 12 working days a year are lost to asthma. This figure does not include the parents who miss work to care for children with asthma (Asthma Society of Ireland 2010).

The Health Service Executive (HSE) (2009) identified the need to make savings of €530 million in its annual budget. The continued deterioration in the nation's finances in 2010 means that the scale of savings required in future years will increase significantly. Any measures that can help achieve these savings without reductions in front line services will be of crucial value. Even more beneficial would be interventions that improve patient care and health, while simultaneously reducing the cost burden on the system.

Although advances in asthma care and medicines treatment have vastly improved in recent years, not everyone is experiencing this benefit. Most people can control their condition and live full, normal lives, however for many low income Irish people with asthma, the high costs of medicines and doctor visits can prove a barrier to effective asthma management.

2.4 The role of the Nursing Profession

The present system of general nursing in Ireland evolved from a long-established tradition of caring for the physically sick in hospital. The aim of the nursing profession is to deliver a high quality service, based on reliable and valid research. At its core, nursing research is guided by a caring ethos, but it is also concerned with the quality of its research which has a direct impact on the quality of care (Kelly and Long, 2000). The delivery of nursing care by safe autonomous and accountable practitioners is advocated by An Bord Altranais (2000) and places individual accountability with the nurse to develop and maintain the competence necessary for professional practice.

Nurses must be aware that they are accountable for their nursing practice and for working within their scope of practice (An Bord Altranais, 2000) and so nurses

involved in educating patients must acquire the competencies and skills of an educator. These include knowledge of the clinical area, principles of learning, understanding of change theory, the need for effective communication, and the application of educational tools (Manning, 2004).

Health promotion and primary prevention of disease by nurses has evolved into an essential and critical aspect of their role and is practised across many therapeutic areas (Benson and Latter, 1998; Cutler 1999).

Whitehead (2004) defines health education as:

"*An activity that seeks to inform the individual on the nature and causes of health/illness and that individual's personal level of risk associated with their lifestyle-related behaviour.*" (Whitehead 2004, p313).

Whitehead goes on to say that health education should seek to "*motivate the individual to accept a process of behavioural-change thorough directly influencing their value, belief and attitude systems, where it is deemed that the individual is particularly at risk or has already been affected by illness/disease or disability*".

The International Council of Nurses (ICN) estimates that there are approximately 12 million nurses worldwide. These nurses - with an understanding of the dynamics of adherence and the ability to understand the problems associated with adherence - present a formidable force in improving adherence and compliance care outcomes.

Nursing interventions identified by the WHO to improve adherence include:

- interview techniques to pose non-threatening questions to assess the level of non-adherence,

- asking about medicinal side effects and the effect on the patient's quality of life,
- educating the patient on their illness and associated remedies,
- re-inforcing the education with the patient.

Nurses in the health care setting are employed through numerous different areas and roles. These include the public health nurse, midwives, general nurses, palliative care nurses, psychiatric nurses, mental health and intellectual disability nurses, practice nurses, school nurses, and specialist nurses (National Council of Nurses and Midwives (NCNM) 2008b, Commission on Nursing 1998). These different nursing groups provide a nursing service, which incorporates prevention, treatment and rehabilitation. For the purposes of this literature review the writer will focus on the role and function of the respiratory nurse specialist.

2.4.1 The Nurse Specialist

The Respiratory Nurse Specialist role has evolved since the early 1980's, when the Working Party on General Nursing noted the need to develop specialist nurses to enhance the quality of nursing care.

The role was initially developed to provide specialist nursing service in certain nursing areas; to advise other nurses in these areas; and to provide a career pathway to nurses wishing to seek a career in clinical nursing. In 1998 the commission on Nursing acknowledged the role and recognised the need for a coherent approach to the programme of development and specialisation of a clinical career pathway for nurses and midwives. As a result of this The National Council for the Professional Development of Nursing and Midwifery (The National Council) devised the definition and criteria for nurse specialist roles. The application process was handled by the National Council and the newly formed Nursing and Midwifery Planning and Development Units (NMPDUs).

Simultaneously specialised education programmes were created and developed to deliver specialist nursing and midwifery modules within the third level education sector. The role was intended to meet the needs of patients in terms of rehabilitation, for example, supervising nebulised therapy and working in disease specific areas such as asthma, cystic fibrosis and COPD. The nurse specialist role involved the education of the patient in understanding their condition and how to manage it. The role has since developed further with the provision of nurse-led clinics.

The NCNM (2008) describe the role of the nurse specialist as a defined area of nursing or midwifery practice that requires the application of certain knowledge and skills to improve the quality of patient care. The role has a major clinical focus, comprising the assessment, planning, delivery and evaluation of care given to patients and their families in hospital, community and outpatient settings. The NCNM definition confirms that:

- the specialist nurse will liaise with medical and para-medical colleagues and may alter prescribed clinical options within the boundaries of agreed protocol driven guidelines.
- the specialist nurse will participate in nursing research and provide advice in education and clinical practice to nursing and interdisciplinary team.
- the specialist nurse will have undertaken formal recognised post-registration education relevant to the area of practice and this education is underpinned by extensive experience in the clinical area.

Research is needed to ascertain the effectiveness of nurse specialists. A study by Nathan *et al.* (2006) showed that follow up care by a respiratory specialist nurse of patients admitted with acute asthma can be delivered with an effectiveness and safety comparable with that given by a doctor. This finding is similar to that done by Van den Hout *et al.* (2003) who assessed the relative cost effectiveness of nurse

specialist care, inpatient team care and day patient team care in patients with rheumatoid arthritis found that the care provided by the nurse specialist was the preferred treatment from a health economic perspective.

2.4.2 Nurse-led care

Nurse-led care is distinct from nurse-coordinated or nurse-managed services. Nurse-led care is provided by nurses responsible for case management, which includes comprehensive patient assessment, developing, implementing and managing a plan of care, clinical leadership and the decision to admit or discharge. The potential for nurses and midwives to further enhance the development of high quality patient-centred care and to influence positive patient care outcomes is considerable. Patients are referred to nurse-led services by nurses, midwives or other healthcare professionals, in accordance with collaboratively agreed protocols. Such care requires enhanced skills and knowledge and the nurse needs preparation in both the clinical and management aspects of the role

As stated earlier, nurses are accountable for their working practice and must work within their scope of practice and have the necessary competencies to do this. Various frameworks exist that can be used when identifying areas for expansion of practice. These include: Scope of practice (An Bord Altranais, (ABA) 2000), Code of conduct (ABA, 2000a), ANP/AMP framework (4th ed) (National Council, 2008a), CNS/CMS frameworks (4th ed) (National Council, 2008b), and ABA guidelines for midwives (ABA, 2001).

The services provided by nurse specialists include comprehensive patient assessment, development, implementation and management of plan of care, and clinical leadership. Patients are referred to these services by nurses, midwives and other healthcare professionals (NCNM, 2008b).

It is important to stress that nurse-led/midwife-led care is delivered within the context of a multidisciplinary/partnership approach. No one healthcare professional should provide all the care that patients/clients may need over the span of a lifetime. All healthcare professionals work within the scope of their own competency, having the ability to recognise boundaries and knowing when to consult with other professions.

It has been shown in numerous studies in different disease groups that nurse case management, disease management and population-based management have all resulted in improved adherence/compliance to the recommended standard of care with improved clinical and economic outcomes (Aubert *et al.* 1998; Sadur *et al.*1999).

Richardson *et al.* (2000) have shown that adherence to hypertension therapy would benefit from intervention by nurses. Tapp *et al.* (2007) reviewed the literature from 12 studies with 1954 patients, examining education interventions for adults who attend the emergency room for acute asthma; it was found that in six studies that there was a statistically and clinically significant decrease in subsequent hospital admissions; there was also a lower cost of emergency department visits per person per year associated with the educational interventions. Importantly in one study it was discovered that significantly more patients had adequate inhalation techniques and were aware of their peak flow reading in the education group when compared to the control group.

This review surmises that people with asthma and asthma attacks frequently attend emergency departments, which lead to hospitalization. The frequency of these attendances for acute asthma has led to research investigating the use of non-pharmacological interventions to reduce the future use of health care. Hospital admissions could be prevented if individuals with asthma could use an asthma action plan, improve their knowledge of asthma, adhere to preventive treatment,

initiate medication early during an attack, and seek medical assistance early if their condition does not improve (Tapp *et al.* 2007).

A systematic review by the Cochrane Airways Group concurs with this assessment. Training patients in asthma self-management, self-monitoring of their peak flow and/or symptoms allied with medical review and written action plans appear to improve health outcomes, reduce hospitalizations and unscheduled doctor visits (Gibson *et al.* 2002). The same review also notes that limited education such as information only does not improve health outcomes.

Bolton *et al.* (1991) used a registered nurse to teach small groups of patients in three 1–hour education sessions about the importance of medication, adherence to treatments control and prevention of asthma attacks, relaxation techniques and smoking cessation. The education only cost $85 per person per annum, but subsequently reduced the cost of emergency department visits by $623 per person during the following year. Indirect costs were also reduced by 35% compared to the control group.

In a similar study Greineder *et al.* (1998) used a single outreach nurse for 8 hours per week to instruct and educate patients in asthma management, medications, triggers, inhaler technique and use of peak flow meters. The outcomes were that the annual rate of paediatric emergency department admissions related to asthma was reduced by 79% and hospital admissions were reduced by 86%. In addition the nurse maintained regular telephone contact with the families to ensure compliance with their treatment plans. At a cost of $11,115 per year this nursing intervention saved $ 87,000 in 1993.

The literature reviewed above highlights that the links between education and self-management is best practice in asthma control and adherence. In improving adherence/compliance issues, nurses have diverse skills that must be tapped. Nurses

need education programmes to improve their competency and awareness about the importance of adherence in health care.

In the specific context of dealing with asthma, this literature review highlights that patient education is a critical factor in the management and control of the disease, and that education must extend beyond the nurse to include all health professionals working with the patient.

2.5 Defining Asthma

Asthma is a chronic airways disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person. Symptoms may occur several times a day or week in affected individuals, and for some people symptoms become worse during physical activity or at night (World Health Organisation (W.H.O.), 2010). Intermittent relapse from periods of stable asthma is the usual clinical course for most adults.

The GINA definition states that as there is no clear pathogenesis, much of the definition is descriptive. An operational description of asthma is:

"Asthma is a chronic inflammatory disorder of the airways..... that leads to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread, but variable, airflow obstruction within the lung that is often reversible either spontaneously or with treatment" (GINA, 2002).

Asthma exacerbations may be caused by a variety of triggers, including allergens, viral infections, pollutants and drugs. Reducing exposure to some of these risk factors helps improve the control of asthma and reduces medication needs. Many patients react to multiple factors in the environment. Avoiding these factors is usually impractical and very limiting for people with asthma and allergies. Medications to maintain asthma control have an important role because patients are

often less sensitive to risk factors when their asthma is under good control (Asthma Society of Ireland, 2010).

During an asthma attack, the lining of the bronchial tubes swells, causing the airways to narrow and reducing the flow of air into and out of the lungs. Recurrent asthma symptoms frequently cause sleeplessness, daytime fatigue, reduced activity levels and school and work absenteeism. Asthma has a relatively low fatality rate compared to other chronic diseases (W.H.O., 2010).

2.5.1 Diagnosing Asthma

Asthma is diagnosed clinically. A correct diagnosis is essential to ensure that the correct treatment is given. A clinical diagnosis is prompted by symptoms such as breathlessness, wheeze and cough. A full medical history is necessary, including family history and triggers, such as exercise, upper respiratory infection, heightened emotions, or exposure to animals, smoke, or cold air. The patient should be asked about a history of nocturnal coughing or whether he awakens short of breath; either of these may indicate asthma.
Physical examination is seldom diagnostic of asthma unless the patient is having an exacerbation and other symptoms are also present (Owen 1999; GINA updated 2009).

Pulmonary function testing (spirometry) is used to evaluate the degree of airway obstruction and to determine the presence of bronchial hyper-responsiveness (Owen, 1999). Spirometry is also helpful with both the diagnosis and monitoring of asthma. Pre- and post-bronchodilators testing should be carried out to observe the improvement in lung function post medication. It is important to state that undertaking spirometry requires cooperation between the patient and the examiner as the results obtained will depend on technical and personal factors. Proper instruction on forced expiratory effort must be given to the patient and the highest values of three recordings are taken. Quality control of the equipment is also key to

providing accurate diagnosis of the disease and it is strongly recommended that spirometry equipment be calibrated daily (Gina updated guidelines, 2009).

However, because pulmonary function measurements are usually taken infrequently, or only when patients are being treated for exacerbations, these tests may not fully represent the condition. Patients should be encouraged to use peak flow meters twice daily at home and to maintain a frequent record of pulmonary function so that the severity of asthma and response to therapy can be assessed. This is an important aid in the diagnosis and management of asthma (Owen, 1999). GINA (2009) has published global guidelines to improve the diagnosing of asthma, and to promote standardised methods for the diagnosis and treatment of the disease. These guidelines have been distributed widely throughout the world; there are several reports to indicate that doctors are aware of the recommendations (Rabe *et al.* 2000; Schneider, 2007). However, even though these guidelines are recognised by doctors, there are patients who are not treated accordingly (Rabe *et al.* 2000; Schneider, 2007).

2.5.2 Asthma Severity

Severe Asthma in Ireland and Europe - a Patient's Perspective (2007) states that for the majority of people with asthma the condition is relatively mild and has little or no impact on their lives; however this is not the case for the 6300 people in Ireland who suffer from severe asthma. Severe asthma is identified if one of the following criteria is met:

- Sleep disturbance once a week or more often,
- A wheezing attack once a week or more often,
- One or more speech limiting attacks.

Determining the severity of asthma is necessary as treatment guidelines are based on the severity of the patient asthma. Severity is determined by the history of

frequency, asthma symptoms, activity levels, the need for rescue medication, and by pulmonary function measurements.

Several factors can complicate the assessment of asthma severity. First, disease classification is based on the symptoms the patient had before starting treatment. Once treatment has begun, classification becomes more difficult. Second, asthma is a variable disease. Studies have shown that patients with asthma rarely remain in the same category over time, and that patients themselves often underestimate their symptoms and thus are classified incorrectly (Mintz, 2004).

Previous GINA documents subdivided asthma by severity into four categories, based on the level of symptoms, airflow limitation and lung function variability. These are: intermittent, mild persistent, moderate persistent, or severe persistent (based on expert opinion rather than evidence).

It was thought that accurate assessment of severity may motivate a patient to adhere to the prescribed regimen, or to seek out advice for regimen modification from a health care provider (McGann, 1999). In one study it was found that patients tended to underestimate their severity and over estimates their control; over half these patients with severe disease perceived their asthma to be well controlled even though they had a low quality of life and utilized a high level of health care (Rabe *et al.* 2000).

Now, the classification of asthma by severity is no longer recommended as the basis for on-going treatment decisions (Bateman *et al.* 2008). According to GINA updated guidelines (2009), asthma severity is now classified on the basis of intensity of treatment required to achieve good asthma control. Mild asthma is where control is obtained with low intensity treatments; severe asthma is where control is achieved with high intensity treatments or control is not achieved despite high intensity treatments (GINA, 2009).

2.5.3 Incidence

The W.H.O. estimates that 300 million people currently suffer from asthma. It is the most common chronic disease among children. In Ireland 1 in 8 of the population are affected. The National Asthma Education and Prevention Program (NAEPP) (2010) guidelines note that under-diagnosis and inappropriate therapy contribute substantially to asthma morbidity and mortality. The Asthma in Ireland Report (2011) notes that there are eighty to one hundred asthma-related deaths reported in Ireland each year. This is over one death a week (Asthma Society in Ireland 2011).

There has been an increase in the prevalence of the condition; if the trend continues it is estimated that there will be an increase of 100 million in the number of asthmatics worldwide by 2025 (Gina, 2006). Ireland has the 4th highest prevalence worldwide. The prevalence in 13 - 14 year old Irish school children increased by 40% from 1995 to 2003 (15.2% to 21.6%). Asthma is the most common chronic disease in childhood and the most common respiratory condition in Ireland (Asthma Society of Ireland, 2009).

The INHALE Report (2008), states that diseases of the respiratory system are responsible for one fifth of all diseases in Ireland. The INHALE Report (2008), notes that in Ireland, respiratory disease is the most common reason for people to visit their G.P. Approximately 25,000 A/E visits per annum are asthma-related and there are 6,000 to 7,000 asthma-related admissions to Irish hospitals every year (Severe Asthma in Ireland and Europe - a Patient's Perspective 2007, Asthma Society of Ireland 2010)Therefore, increased resources to better manage the disease are required if this trend is to be reversed (INHALE, 2008).

As a response to this increasing prevalence, guidelines to standardise the method of diagnosis and treatment were developed which gave rise to the publication of the Global Initiative for Asthma (GINA).

2.6 Management and Control of Asthma

Over 12% of the entire Irish population now suffers from asthma and management of the condition is poor, with up to 90,000 (almost 20%) of those affected failing to keep it under control (Asthma Society of Ireland, 2010). The development and implementation of effective management and control methods is therefore of critical importance in tackling asthma. The national and international recommendations for asthma management are described in five interrelated components of therapy and have the following major goals:

- to achieve and maintain control of symptoms,
- to maintain normal activity levels, including exercise,
- to maintain pulmonary function as close to normal as possible,
- to prevent asthma exacerbations,
- to avoid adverse effects from asthma medications, and
- to prevent asthma mortality.

(British Guideline on the Management of Asthma 2007, Bateman *et al.* 2004).

The Global Initiative for Asthma (GINA) and The National Asthma Education and Prevention Program (NAEPP), have issued an update of selected topics in the Guidelines for the Diagnosis and Management of Asthma. The guidelines now focus on 4 main areas:

- Measures to evaluate and monitor asthma control,
- Patient education,
- Control of environmental exposures known to trigger or exacerbate asthma symptoms,
- A combination therapy of a long-acting inhaled steroid and long-acting beta -2 -agonist as safe, effective and preferred first-line therapy for children as well as adults with persistent asthma (GINA, 2006; NAEPP, 2007).

NAEPP (2010), states that asthma self-management education is essential to provide patients with the skills necessary to control their asthma and to improve their outcomes. This education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement.

Asthma self-management should begin at the time of diagnosis and continue through follow-up care. It requires the development of a partnership between the person with asthma and all members of the health care team. The aim of this partnership is to guide the patient through a self-management asthma action plan which will give the person with asthma the ability to control their own condition under the guidance of their health care professional (Bateman *et al.* 2008). Chronic illness patients are likely to adhere to therapy if they trust the provider who prescribes the regimen, if there is evidence that the regimen is effective and does not cause distressing or frightening side effects that outweigh any therapeutic benefits, if the regimen does not significantly interfere with important daily activities, and if it does not have a significant impact on the individual's sense of identity (Strauss and Glaser, 1975).

Regular review, by an informed clinician, of the status of the patient's asthma control is an essential part of asthma self-management education. The health care team should take every opportunity to teach and reinforce:

- Basic facts about asthma,
- How medications work,
- Inhaler technique, (patient should repeat demonstration)
- Environmental control measures,
- Written asthma action plan.

The goal of asthma treatment is to take control of the symptoms and improve the quality of measurement by a whole series of parameters which include symptoms, lung function, exacerbation rates, inhaler medication usage and quality of life.

2.6.1 Treatment Options

Management of Asthma becomes suboptimal when physicians fail to prescribe appropriate therapies (Ramsey, 2000) which are set down in the guidelines. The patient's current level of asthma control and current treatment determine the selection of pharmacological treatment. For example, if asthma is not controlled by the current treatment regimen, treatment should be stepped up until control is achieved. If control has been maintained for ≥3 months, treatment can be stepped down with the aim of establishing the lowest step and dose of treatment that maintains control (Bateman *et al.* 2008).

Asthma treatments can be classified as controllers or relievers.

Controllers, for example inhaled glucocorticosteroids, are taken daily on a long term basis and help keep asthma under control through their anti-inflammatory effects. Long acting inhaled β_2- agonists (LABA) are also controllers, but are never used as a mono therapy for asthma as there is no influence on the airway inflammation in asthma; however they are effective when combined with glucocorticosteroids. This combination is the treatment of choice when a medium dose of inhaled glucocorticosteroids fails to control asthma. However, adherence to corticosteroid treatment regimens remains problematic, and will be discussed in more detail later.

Relievers, for example short acting inhaled β_2- agonists (SABA), provide rapid relief from bronchospasm during an asthma attack. Anticholinergics may also be used if the patient experiences side effects to the SABA, such as tachycardia and tremor (Bateman *et al.* 2008).

Patients also struggle to get the maximum benefit from their medications. Common problems include:

- Poor inhaler technique and routines,

- Difficulty in timing their inspiration with the medication dispersal,
- Using empty containers,
- Using inhalers in public (Owen, 1999).

Prescribing medication is a common intervention in health care and there is evidence to support that taking medication correctly improves health outcomes (Horne *et al.* 2005). It is possible to achieve asthma control with the medication treatments available, albeit in the setting of a clinical trial where patients are more likely to be compliant; but in the real world patients make choices (Bateman *et al.* 2004; Horne *et al.* 2007). There is evidence to suggest that patients are consistently not taking their medication as directed (Kaufman and Birks, 2009). This is relevant to all conditions including respiratory conditions (Horne *et al.*2005).

2.6.2 Inhaler Technique

It is well recognised that the preferred delivery of medication treatment in asthma is via an inhaler because the medication reaches the target organ. There is also the advantage that less medication is required compared to oral methods, which in turn reduces the systemic side effects (Lavorini *et al.*2008; Burns, 2009).

Correct inhalation technique alongside appropriate drug therapy is vital in effective asthma therapy. Incorrect inhaler usage is a significant problem in asthma management, as therapeutic effect may be diminished, resulting in poor control of asthma symptoms. Patients may receive treatment, but without proper education and training in inhaler technique, the therapeutic benefit is below optimal (Lavorini *et al.* 2008). In a review of 394 randomised controlled trials, Dolovich *et al.* (2005) report that there were no significant differences in any efficacy outcome of patients with Asthma or COPD. Restrepo *et al.* (2008), note that where used correctly by the patient, there is little difference in clinical efficacy between different inhalers. However they also note that whichever device is chosen, patient benefit depends on the ability of the patient to use the device and on their adherence to the dosing regimen.

Patient errors in the use of inhaler devices are common (van Beerendonk *et al.* 1998). Many inhalers are difficult to use, with some requiring eight steps for a correctly performed inhalation manoeuvre. Restrepo and Gardner (2010) report that the ability of the patient to use the prescribed device plays a critical role in therapeutic outcomes.

Restrepo *et al.* (2008) note that patient technique is a process that encompasses an individual's previous experiences, education, abilities, and the teaching received on the specific device. To acquire the necessary skills, both health professionals and patients need adequate education and training.

Poor inhaler technique is associated with poor asthma control (Crompton *et al.* 2006). Although health care professionals involved in the management of patients with respiratory disease are expected to be versed in the use of all available inhalers, the reality is quite different. Sestini *et al.* (2006), report that primary care physicians are not familiar with relevant features of currently available inhalers. Health care professionals have a responsibility to ensure that patients use prescribed medications correctly; however this cannot be achieved if the educators have questionable skills.

Crompton and Barnes (2006) note that some healthcare professionals have a 'blind spot' when faced with inhaler technique. To correctly teach inhaler use, healthcare professionals such as nurses, doctors and pharmacists should have adequate knowledge about inhaler use, as poor knowledge leads to poor patient asthma control. Repeat training programmes for health professionals is necessary to improve their knowledge on inhaler technique (Kishore *et al.* 2008). In Benin City Nigeria, a study of 51 pharmacists was carried out to determine their level of knowledge with regard to proper inhaler technique and the effect of an educational intervention on that knowledge. The study used the 11 step criteria developed by NAEPP for the knowledge and proficiency of a metered dose inhaler by subjects.

Post education knowledge was assessed again using the same criteria. It was found that 7 of the respondents failed all steps and only 1 respondent got all of the steps correct. After the educational intervention, 17 of the respondents got all of the steps right. This study did not ascertain the long term benefits of such an intervention but did conclude that regular education of pharmacists on the use of all inhaler devices would benefit patient care (Odili and Okoribe 2010). It is not enough that the patient is competent in the use of inhalers. No single inhaler is good enough until both the health care provider and the patient can demonstrate adequate level of competency in the use of the device.

Laforest *et al.* (2006) carried out research on 348 French asthma patients. In France, patients may be supervised by general practitioners and/or specialists. The study examined asthma management in patients supervised by specialists only, by general practitioners only, and by both specialists and general practitioners. Their findings showed marked differences in symptoms and asthma management according to the type of asthma supervision. These results support the need to improve the management of asthma in primary care, and the coordination of care between general practitioners and specialists.

2.7 Adherence / Compliance

Non-adherence / non-compliance to treatment regimens are a constant challenge to nurses and other health professionals and it is well known that adherence rates are a problem in patients with asthma (Takemura *et al.* 2010). Nurses are aware of the consequences of non-adherence and of the associated costs to the patient, community and health care system. Nurses are also aware of the frustrations that the patient experiences about treatment failures, poor health outcomes and patient dissatisfaction that are associated with poor adherence / compliance (WHO, 2003). Compliance or adherence is not easily attained, and is affected by a multitude of issues relating to the patient, the doctor and the treatment of a chronic condition such as asthma.

It has been reported by the WHO (2003) that over 50% of patients on long-term pharmacotherapy has problems with adherence. There can be many reasons for this, varying from complexity of daily medication regimen to their relationship with the primary care provider (Restrepo *et al.* 2008). In addition, many people use multiple inhalers containing their different treatments, so keeping track of daily dosing schedules can be difficult (Dolce *et al.* 1991; Steinman *et al.* 2006).

Adherence is defined as "the extent to which the patient's behaviour matches agreed recommendations from the prescriber" (NICE). Haynes *et al.* (1979) define adherence as "the extent to which a person's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice".

As referred to previously, the preferred delivery of medication treatment in asthma is via an inhaler because the medication reaches the target organ. The adherence to inhaled combination medications is usually tracked through reading of a counter on the inhaler casing that indicates the number of doses dispensed. However these counters do not provide information on either the timing, or technique, of use of the recorder, both of which are important in achieving clinical response to therapies. Management of Asthma becomes suboptimal due to poor adherence to evidence based guidelines and under-diagnosis (Ramsey, 2000), or when patients fail to adhere to prescribed treatment regimens (George *et al.* 2005; Sestini *et al.* 2006). Adherence to medication regimens is often suboptimal when patients are on long-term pharmacotherapy using repeat prescriptions (WHO, 2003). Adhering to inhaled medications is of paramount importance in the management of patients with Asthma.

Simple instructions in asthma self-management improve adherence with inhaler devices but despite this, improvements can decrease over time - even with return clinic visits (Lasmar *et al.* 2009; Rau, 2005). The problem of adherence is compounded by the fact that more than one inhaler is often required. For example,

when 2 medications are prescribed, approximately 50% of patients are adherent to only one. (Corden *et al.* 1997; Schlenk *et al.* 2004) Several researchers have reported that more than 10% of hospital admissions are as a result of medication non-adherence (Corden *et al.* 1997; Schlenk *et al.* 2004).

The National Collaborating Centre for Primary Care (NCCPC) (2009) state that while the there are many causes of non-adherence, they can be summarised into two overlapping categories: intentional and unintentional non-adherence.

- ***Intentional non-adherence*** is when the patient decides not to follow the recommendations. Refusing to take medication for fear of adverse effects constitutes intentional non-adherence (Rau, 2005).

- ***Unintentional non-adherence*** occurs when the patient agrees to the treatment but is prevented from doing some by reasons beyond their control. Examples include poor comprehension and or recall of instructions, a difficulty in administration of their treatment, or simply forgetting to take their medication.

Takemura *et al.* (2010) concur with this.

Failing to understand correct use of an inhaler exemplifies unintentional non-adherence (Rau, 2005), The inability of patients to understand the advice given to them by the health professional and also the inability to learn the necessary self-management skills leads to frequent presentation at the emergency departments for asthma-related reasons (Balkrishnan *et al.* 2003).

There has been much research into the area of adherence and non-adherence. The following section gives a flavour of some of the findings.

The WHO (2003) recognised the multidimensional nature of non-adherence and described it as being determined by "the interplay of five sets of factors",

- Patient-related,
- Condition-related,
- Therapy-related,
- Health-system related, and
- Socioeconomic-related.

Elliott (2006) in a review of asthma literature categorised adherence factors under the following Patient Characteristics:

- Age,
- Socioeconomic Status and Education,
- Ethnicity,
- Social Support,
- Depression,
- Patients' views on their illness.

Rau (2005) states that factors related to adherence include:

- The type of inhaled agent,
- the complexity of the inhalation regimen (e.g. dosing frequency, number of drugs),
- route of administration (whether oral or inhaled),
- patient awareness of monitoring, and
- various patient beliefs and sociocultural and psychological factors.

Horne *et al.* (2005) have looked at the many influences on medicine-taking by patients, and have summarised the various internal and external factors that impact on the patient's adherence \ non-adherence, as shown in Figure 1.

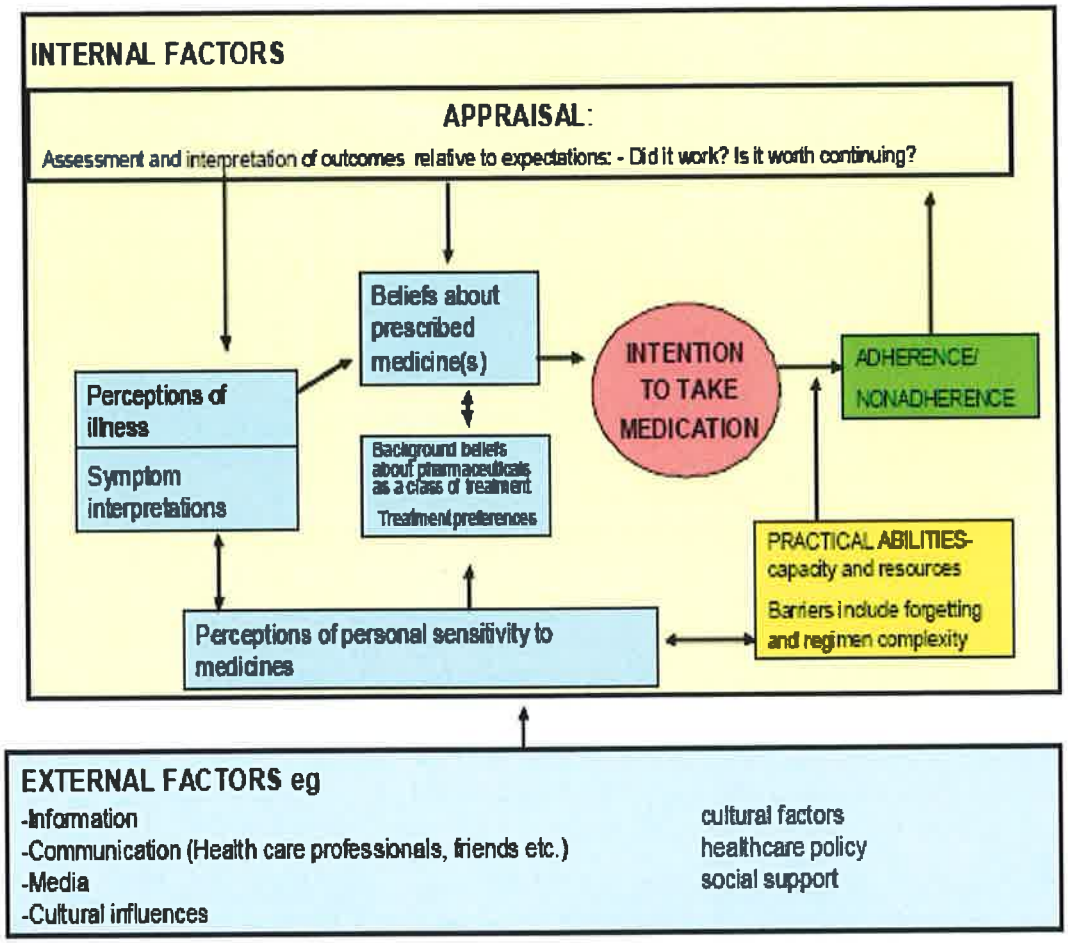


Figure 1. Concordance, Adherence and Compliance in Medicine-Taking.

Their analysis is of particular interest in the way that it assesses how a patient's perceptions and attitudes influence their adherence \ non-adherence.

Bender (2005) reviewed 29 different studies in which patients (adults and children) had themselves identified barriers to adherence and as a result compiled the following table of factors.

Patient group	Patient-identified barriers
Adults	Fear of adverse effects of medication Belief that the medication does not work or is not necessary Sense of only an intermittent need for medication Inconvenience of medication use Cost of medication Dislike of provider Interference of life hassles Distrust of medical establishment Less important factors: stigmatization, inadequate knowledge, forgetfulness, belief that asthma is not serious, worry about diminishing effects over time, fear of addiction, lack of social support
Children and/or their parents	Stigmatization Fear of adverse effects of medication Fear of addiction Difficulty with administration of medication Dividing responsibility for treatment among children and caregivers

Figure 2. Barriers to adherence as identified by adults and children

Their analysis confirms that there a wide range of factors that impact on a patient's overall compliance with their medication regimen, and that different patient groups can have different concerns.

Dolce *et al.* (1991) produced the following analysis of common causes of poor adherence in patients with COPD:

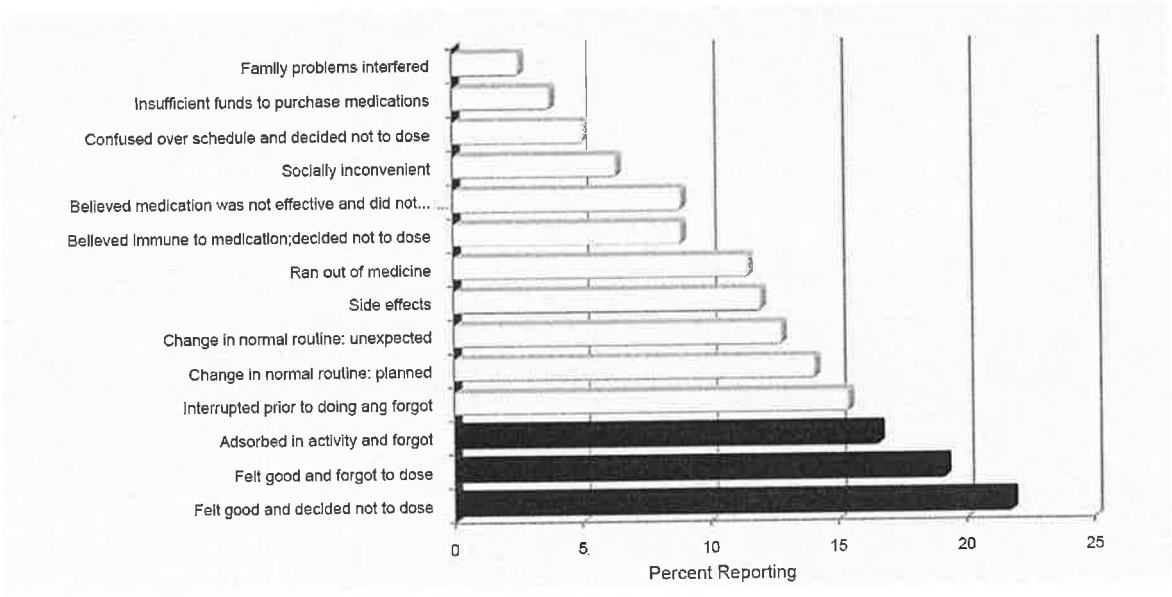


Figure 3. Common causes of poor adherence. Solid bars indicate top three reasons cited for missing medications.

Again, the data shows many factors that can lead to non-conformance; here the top factors are particularly concerning because they highlight how easily patients can be moved \ distracted from their medication obligations.

In looking at adherence issues in patients with COPD, Restrepo *et al.* (2008) refer to the three classic types of non-adherence to therapy: underuse, overuse, and improper use.

Underuse is defined as a reduction of the daily use of a standard dose of a medication that is indicated for the treatment or prevention of a condition. Although underuse can result in morbidity and health care cost, the cost of the medication is believed to be one of the most important determinants of underuse (Hanlon *et al.* 2001; Stuart, 2004; Maio *et al.* 2005).

Overuse: In patients with COPD, underuse is followed in frequency by overuse and improper use of the medication delivering device. There is evidence of overuse of

short-acting inhaled β_2- agonists in patients with asthma (Lynd *et al.* 2002), although this study based its results on computerized dispensed medication data, and not on the actual medication intake by the patient. During respiratory distress, approximately half of patients report using more than the prescribed amount of medications (Dolce *et al.* 1991; Bosley *et al.* 1995).

Improper use is the most frequent type of non-adherence in patients older than 65 years with polypharmacy (Steinman *et al.* 2006). Misuse of inhaler devices is associated with decreased asthma control, increased risk of hospitalization, increased number of visits to emergency room and increased courses of oral steroids (Giraud, 2002; Melani *et al.* 2011). Sestini *et al.* 2006, in conducting an observational study of 1,305 patients on their use of inhalers, found that misuse was significantly and equally associated with older age, less education, and less instruction by health care personnel. The two most common reasons for a medication to be considered inappropriate are lack of effectiveness and lack of indication (Hajjar *et al.* 2005; Steinman *et al.* 2006; Rossi *et al.* 2007).

While the fundamental principle of prescribing is based on the use of the most clinical and cost-effective medication and device, choices may become influenced by factors that are not clinically relevant or evidence-based. The ability of the patient to use the prescribed device affects adherence to treatment. Patients may become frustrated if their preferences in treatment-related decisions are not sought and taken into account (Webb *et al.* 2001; Restrepo *et al.* 2010). Clinical benefit also depends on the ability of the patient to use the device and on their adherence. Real-life observational studies that evaluated patient inhalation techniques have shown frequent improper use of inhalers.

2.8 Inhalers and dosing technique

Much research has been undertaken over the years into the design and use of inhalers, and the impact of technique on efficacy. McFadden (1986), reports that patients may be using their inhalers improperly, even though they are adhering to

their dosing schedule. Research has also shown that inhaler-specific design features contribute significantly to the patient's adherence to treatment (Brown *et al.* 1992; Woodman *et al.* 1993).

The typical method to evaluate inhaler technique is by assigning a score on the number of steps performed correctly out of the total number of possible steps. An evaluation of inhaler use in 316 patients suffering from asthma or COPD found that 89% of the patients made at least one mistake in the inhalation technique (van Beerendonk *et al.* 1998). The most common skill error was "not continuing to inhale slowly after actuation of the inhaler" (69.6%). The non-skill item most patients had difficulties with was "exhaling before the inhalation" (65.8%). The most frequent problem identified was failure to coordinate actuation with inhalation and to hold their breath after inhalation.

Bosley *et al.* (1995) asked simple questions to establish if patients had a basic understanding of their nebulized medication and found that 52% of patients were not able to answer these questions correctly - although 91% believed that they did understand the treatment they were prescribed. Of those who were unable to answer correctly, 60% were found to be non-adherent.

The WHO (2001) in its *Report of the Commission on Macroeconomics and Health* states that without a system that addresses adherence, advances in biomedical technology will fail to realise their potential to reduce the burden of chronic illness. Access to medications is a necessary, but is insufficient in solving the problem of chronic illness. Haynes (2008) concurs and suggests that because of the alarmingly low rates of adherence, increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.

No matter how effective a treatment or how diligent a person in adhering to that treatment, chronic illness will never be completely obliterated. This may explain

why the importance assigned by an individual to his therapy rarely matches that of the clinician. An individual creates a personal standard of compliance, while his clinician has a professional standard, one that is not always easily maintained in daily life (McGann, 1999).

Where non-adherence occurs, it should not be seen as purely the patient's problem, but rather a limitation in the delivery of healthcare (The National Collaborating Centre for Primary Care (NCCPC), 2009). There needs to be agreement between the healthcare professional and the patient about the treatment, and prescribed medication. Good communication skills in clinicians and patient education about inhaled medications are central to improving adherence (Rau, 2005).

Addressing non-adherence is more than just about getting patients to take their medication – it involves understanding the patient's attitude towards, and ability to use, medicines Horne (2006). As recent advances in the design of medications and the patient-centred approach to health care delivery has not solved the problem of non-adherence, there is a need to develop strategies to make health care delivery more efficient and more focused on patients' needs.

2.9 Impact of teaching

As patient errors in the use of inhaler devices are common, it is therefore important that proper education and instruction on their use is provided to the patient (Fink and Rubin, 2005; Rau, 2005). Inhalers represent advanced technology that is considered so easy to use that many patients and clinicians do not receive adequate training in their use (Fink and Rubin, 2005). And this is compounded by the fact that clinician knowledge of correct use of inhalers has been shown to be imperfect (Rau, 2005).

Inhalation therapy is a complex procedure and education between physicians and users is necessary in order to achieve the best results. Patients need to be involved by their clinician in the management of their asthma. It is vital that the patient is convinced by the clinician that without correct use and maintenance of their inhaler, the clinical result will be reduced or eliminated.

Although inhaled medications have the advantage of targeting the airways they can be difficult to use, requiring numerous steps; also symptom control can require combination therapy of two or more types of inhalers. This means that patients have to master different device-specific instructions (Press *et al.* 2011).

Even though patients may read the instruction leaflet provided, and receive face-to-face instruction in the use of their inhaler, it is vital to evaluate whether or not they are able to use the device correctly. It has been observed that even immediately after face-to-face instruction; patients make mistakes in the use of their inhaler (Brocklebank and Ram, 2001). Physicians, nurses, and pharmacists who care for patients with respiratory diseases should be familiar with issues related to performance and correct use of inhaler devices. Clinicians who care for patients with asthma must understand how to use, select, and match the best device for the individual patient (Fink *et al.* 2005). Medical staff needs to pay more attention to the educational aspects of inhalation therapy.

Regular patient training, provided by medical staff, represents an efficient strategy for reducing errors in inhalation technique. This should include checking the patient's use of the inhaler (and correcting any errors) at each follow-up visit (Sestini *et al.* 2006).

Sestini *et al.* (2006) have noted that many physicians are not familiar with the relevant characteristics of currently available inhalers; and many health care practitioners knowledge of the use of aerosol devices is less than adequate (Hanania *et al.* 1994). Regular instruction, supervision, and checkup of inhalation technique are the responsibility of the treating physician. However, in reality, inappropriate use of inhalers is common and is strongly correlated with a lack of instruction by the caregiver (Sestini *et al.* 2006). In fact Molimard *et al.* (2003) report that primary care physicians only check inhalation technique in 40% of patients who use these devices.

The benefit of providing mere information and well-written instructions without "hands-on" demonstration has been thought as not providing information at all (Sestini *et al.*2006). Koo *et al.* (2006) have noted that a patient's interest in reading the supplied medical information - such as how to use the inhaler - may be influenced by several patient factors. These include: disease state, coping style, health literacy levels, and occupation.

Given that non-adherent patients are more prone to reporting greater confusion about medications, it is likely that health professionals may need to spend more time in the education process, and especially so in the case of elderly patients and those patients with polypharmacy (George *et al.* 2005). Good communication skills among clinicians and patient education about inhaled medications are central to improving adherence (Rau, 2005).

In an observational study of 1,305 patients on use of inhalers, Sestini *et al.* (2006) found that inhaler misuse was significantly associated with older age, less

education, and less instruction by health care personnel. The study showed that more time spent on instruction on proper inhalation technique by health-care providers resulted in better performance. Practical demonstration of proper inhaler use and evaluation of inhaler use at follow- up visits was also strongly associated to better inhalation technique.

Melani (2007) highlights the critical importance of patient education in the use and misuse of inhalers. However Melani also notes that many physicians take for granted that the patient will use the inhaler properly, whereas in reality the majority of patients do not realize that the efficacy of inhaler therapy often depends on whether it is carried out correctly.

GINA (2002) guidelines on asthma indicate that the most important requirement is that the chosen dispenser is used properly. According to Fink and Rubin (2005), between 28% and 68% of patients do not use their inhalers well enough to benefit from the prescribed medication., However they also report that 39-67% of nurses, doctors, and respiratory therapists are unable to adequately describe or perform critical steps for using inhalers.

2.10 Smoking and Asthma

Every month, the National Tobacco Control Office in Ireland (NTCO) monitors cigarette smoking prevalence and behaviour, including the number of cigarettes smoked daily, in order to gain a detailed picture of smoking patterns and to identify trends. For the purposes of assessing prevalence, smoking is defined as responding "yes" to the question "Do you smoke one or more cigarettes each week, whether packaged or roll your own?"

The overall prevalence of cigarette smoking in Ireland as of June 2010 was 23.6%. A higher percentage of men (25.0%) reported themselves as being smokers than did women (22.2%). Smoking rates were highest among younger adults (18-44 years), reaching 30% in the 25-34 year old age group. Prevalence was lowest

among the 65+ age group at 13.5%. One in seven 15-17 year olds (14.3%) were identified as smoking using the NTCO criterion.

The overall prevalence in Ireland is consistent with the findings of Chaudhuri *et al.* (2003), and Thomson and Spears (2005), who report that in most developed countries the prevalence of active smoking in adults with asthma is between 20% and 25%.

The NTCO data indicates that there has been little overall change across categories in the two years up to June 2010. However, the proportion of occasional smokers has increased by almost 2% in the same period, and this has been accompanied by a slight decrease in the proportion of heavy smokers.

Because people with asthma experience respiratory symptoms, it might easily be assumed that they would avoid cigarette smoking. However, Eisner *et al.* (2001) note that previous studies have not adequately addressed whether adults with asthma have a lower prevalence of smoking than the general population. Consequently, they sought to determine whether adult asthmatics are less likely to smoke cigarettes than members of the general population. In a population-based telephone survey, 2902 subjects were randomly selected; it was reported that smoking behaviour among asthmatics was comparable to that of the general population, and that there were no differences in "age of smoking initiation," "duration of smoking," or "intensity of smoking".

When comparing current smokers with asthma and never-smokers with asthma, several studies have reported similar findings i.e. current smokers have more severe asthma symptoms, accelerated decline in lung function, reduced response to corticosteroids, an increase in hospitalisations and increased mortality following near fatal asthma attack (Eisner *et al.*2001; Chaudhuri *et al.* 2003; Thomson and Spears, 2005; Stapelton *et al.* 2011).

Kroon (2007) reports on two sets of research which indicate that the efficacy of inhaled corticosteroids may be reduced in patients with asthma who smoke. In patients with mild asthma receiving 1000 ug daily of inhaled fluticasone the increase in peak expiratory flow at three months was significantly lower in smokers. Another study of patients with mild, persistent asthma demonstrated significantly less improvement in morning peak expiratory function in smokers taking low-dose inhaled beclomethasone (400 ug daily) than in non-smokers.

Several studies have recommended that alternative or additional therapies to inhaled corticosteroids are needed for individuals with asthma who are unable to quit smoking (Eisner *et al.*2001; Chaudhuri *et al.*2003; Thomson and Spears 2005). Stapelton *et al.* (2011) in their review concur with this view. Kroon (2007) advises that practitioners should be aware that patients with chronic asthma may be less responsive to inhaled corticosteroids and should be a targeted for smoking cessation programs.

Kroon (2007) notes that numerous drug interactions exist with smoking, and consequently, smokers taking a medication that interacts with smoking may require higher dosages than non-smokers. Conversely, upon cessation, smokers may require a reduction in the dosage of an interacting medication.

Every effort should be made to encourage individuals with asthma who smoke to stop. Smoking cessation programs that specifically target adults with asthma could have particular efficacy (Eisner *et al.* 2001; Chaudhuri *et al.* 2003; Thomson and Spears, 2005). Recognising that adults with asthma do not avoid smoking should stimulate the development of smoking cessation programs specifically designed for adults with asthma (Eisner *et al.* 2001).

2.11 Weight and Asthma

The prevalence and severity of asthma has been on the increase in the USA and Europe (Vortmann and Eisner, 2008). Simultaneously there is an increase in

overweight and obese adults. Numerous studies link obesity with a higher risk for developing adult-onset asthma (Beuther *et al.* 2006). Lugogo *et al.* (2010) have stated that numerous cross-sectional and case-control studies describe an increased prevalence of asthma in obese and overweight individuals. Lugogo *et al.* (2010) in their review of these studies also find that several large epidemiological studies have reported an increased relative risk of developing asthma in obese individuals, that is, individuals with a Body Mass Index (BMI) >30, suggesting that obesity is a risk factor for the future development of asthma.

2.12 Methodological Discussion

Consideration has been given to the methodological strengths and limitations of the studies referred to throughout this literature review.

Much of the literature reviewed relating to asthma management and control were national and international guidelines GINA and NAEPP which provide evidence based guidelines on the management and control of asthma. Several researchers looked to replicate the guidelines using quantitative methods (Bateman *et al.* 2004) and surveys (Manning *et al.* 2005). Although Bateman *et al.* (2004) achieved the guidelines it was noted that the clinical trial setting was not comparable to real life (Barnes 2004; Horne *et al.* 2007).

Other literature focused on the scale and economic costs of Asthma, and while numbers varied, they all confirmed the globally increasing scale and financial burden (HSE, 2009; AIRI, 2005; Van Ganse *et al.* 2002; Fink, 2005). In a systematic qualitative review of 68 studies focused on the economic costs of asthma, Bahadori (2009) identified both the direct costs of asthma e.g. hospitalization and medication costs and the indirect costs e.g. work and school absenteeism, and perhaps most importantly, reduced participation in family life (Stock *et al.* 2005; Bateman *et al.* 2008).

The literature relating to health promotion and health education highlighted the need for nurses involved in educating patients to acquire the competencies and skills of an educator (Benson and Latter, 1998; Cutler, 1999; Manning, 2004).

The literature relating to adherence to medication and treatments was plentiful and mainly quantitative and related to intentional non adherence and unintentional non adherence (Rau, 2005). Dolovich *et al.* reviewed 394 randomised controlled trials and report that there were no significant differences in any efficacy outcome of patients with Asthma or COPD. Many researchers confirmed that patient benefit depends on the ability of the patient to use the device and on their adherence to the dosing regimen (Laforest *et al.* 2006; Lavorini *et al.* 2008; Restrepo *et al.* 2008; Odili and Okoribe, 2010).
Nurses have diverse skills to improve adherence; however they must receive continuing education to improve their competency and awareness about the importance of adherence in health care (WHO, 2003).

The weakness in the literature is in the lack of detailed programmes for health professionals to ensure that they are fully trained to educate effectively, and in primary-care asthma management programmes that place greater emphasis on regular review of patient compliance and adherence. It would appear from the literature that only through this two-pronged attack will asthma be brought under better management and control.

2.13 Summary

This literature review reveals that asthma is a chronic airways disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person. It affects 300 million people worldwide (WHO, 2009). There are an estimated 470,000 sufferers in Ireland (AIRI, 2005); this number is 3 times what it was just 30 years ago.

According to GINA updated guidelines (2009), asthma severity is classified on the basis of intensity of treatment required to achieve good asthma control. There are four arms to achieving asthma control (GINA 2009), one of which is patient education focusing on inhaler technique. NAEPP (2010), states that asthma self-management education is essential to provide patients with the skills necessary to control their asthma and to improve their outcomes. This education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement. Restrepo and Gardner (2010), report that the ability of the patient to use the prescribed device plays a critical role in therapeutic outcomes.

All of the research on non-adherence highlighted that adherence is about so much more than technique and timing, and is a complex mix of factors: patient-related; condition-related; therapy-related; health-system related; and socioeconomic-related (WHO, 2003).

It is significant that so many of the quantitative studies refer to the importance of education in minimising the impact of asthma on the patient; many researchers highlight the need to improve the management of asthma in primary care, and in particular, the coordination of care between general practitioners and specialists. It is evident that health care professionals are not sufficiently familiar with available inhalers, and their correct use.

Researchers highlight the need for on-going reinforcement of technique to maximise adherence; the literature identifies that patient attitude and buy-in to

treatment regimen are major factors in achieving successful control of asthma. Nurses play a key role in helping to ensure that treatment regimens are followed. They possess diverse skills that must be tapped to improve adherence / compliance and care outcomes. Finally, education programmes improve nurses' competence and awareness about the importance of adherence in health care (WHO, 2003).

Chapter 3 Research Methodology

3.0 Introduction

The purpose of this chapter is to discuss the research methodology used. It will identify the research question and the overall purpose, aims and objectives of the study. The research design best suited to the research question is considered. The study population and the process for gaining access to participants are identified. The sampling method and the data collection method are presented. The technique for analysing the data, ethical considerations and the process of ethical approval are also discussed.

The research design, a quantitative quasi-experimental methodology, was chosen on the grounds that it is the most suitable method to answer the research question (Morse and Field, 2002). The research design is the researcher's overall plan for answering the research question. In a quantitative study, the research design sets out in detail all the strategies that will be adopted by the researcher to obtain information that is accurate and interpretable (Polit et al. 2000).

GINA (2009) identifies four arms to achieving asthma control, one of which is patient education, focusing on inhaler technique. NAEPP (2010), states that asthma self-management education is essential in order to provide patients with the skills necessary to control their asthma and to improve their outcomes. This education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement. Restrepo and Gardner (2010), report that the patient's ability to use the prescribed device plays a critical role in therapeutic outcomes.

It is significant that so many of the quantitative studies refer to the importance of education in minimising the impact of asthma on the patient; many researchers highlight the need to improve the management of asthma in primary care, and in particular, the coordination of care between general practitioners and specialists. It

is evident that health care professionals are not sufficiently familiar with available inhalers, and their correct use. Researchers highlight the need for on-going reinforcement of technique to maximise adherence; the literature identifies that patient attitude and buy-in to treatment regimen are major factors in achieving successful control of asthma.

This insight has led to the design of this study, namely, to examine the impact of nursing education intervention on asthma patients' inhaler compliance, by measuring the patients' inhaler technique before and after an education programme.

3.1 The Research Question

A research question is a statement of the specific query the researcher wants to answer to address a research problem. The research question guides the research method adopted by the researcher (Polit and Hungler, 1999).

The concept for this inquiry came about as a result of the writer's prior involvement in a small pilot unpublished study, which was investigating 20 in-patients who were using an inhaler to which an acoustic device was attached. The purpose of the acoustic device was to record the patients' technique in taking their inhaler.

The data collected during the study period indicated that there were 35% of clinically important errors of inhaler use, comprising of the inhaler being opened twice, leading to double dosing of the medication. The data also identified instances when the device was opened but the lever was not activated - therefore the patient did not receive any medication. The acoustic device recorded events where the patient exhaled directly into the inhaler, thereby wasting the medication; this in turn led to non-medication for the patient. In other identified events, the patient missed one or more of the prescribed doses. Finally, the data also recorded some patients taking more than one extra dose in a 24 hour period.

This small study highlighted that errors in both time of dosing and in the technique of inhalation are very common. The writer felt that the information that was identified could be invaluable to nurses, and could enhance the care and management of patients using inhalers with conditions such as asthma or COPD. Although the literature states the importance of education for patients with asthma, the writer felt that this information was not being retained by the patient, and this formed the basis for the research question for this study.

3.2 Aims and Objectives

The research aims are the specific accomplishments the researcher hopes to achieve by conducting the study and helps to give focus to the study (Polit *et al.* 2000). The research objective may be broader and can include making recommendations for nursing practice based on the study findings (Polit *et al.* 2000).

The aim in conducting this study is to examine the impact of a nursing education intervention on the compliance of patients with asthma in using an inhaler, and to consider the implications of the findings for the role and function of nurses in educating patients.

The objectives in this study can be summarised as follows:

- To describe current practices and asthma patient behaviour in using inhalers,
- To identify deficiencies in the use of inhalers by asthma patients,
- To develop and implement an asthma inhaler education programme for asthma patients,
- To evaluate the impact of the asthma inhaler education programme,
- To make recommendations on best practice in the use of inhalers by patients with asthma.

3.3 The Research Design

The purpose of the research design is to provide a plan for answering the research problem. The research design guides the researcher during the conduct of the study, and in the analysis and evaluation of the data (LoBiondo-Wood and Haber 2006).

In this section the writer will briefly outline the differences between qualitative and quantitative research, and the paradigms that underpin those methods will be explored. Quantitative research methodology is the most appropriate for this study, so the philosophical and theoretical underpinning of this method will be identified and discussed in detail. This will be followed by a short review of the various quantitative research methods available.

Research can provide nursing with a solid knowledge base for nursing practice by seeking to provide answers for questions posed by nurses. The goal is to expand the body of knowledge available (Polit *et al.* 2000). Researchers are required to choose a paradigm to conduct their proposed research. A paradigm is a world-view, a general perspective on the complexities of the real world. Nursing research is

mainly conducted within two broad paradigms: The Positivist Paradigm and The Naturalistic or Interpretive Paradigm (Polit *et al.* 2000).

3.3.1 Quantitative / Qualitative Research

Nursing research utilises both quantitative and qualitative methods of research. The quantitative approach to research comes from a philosophical paradigm which views human phenomena as being open to objective study and it is rooted in positivism (Gerrish and Lacey, 2006). Quantitative research uses methods to collect evidence that can be transformed into numerical data. This approach is used to describe variables and to examine relationships between variables. Underpinning quantitative research is the principle that the world is stable and predictable; the researcher controls external influences and minimises bias that might give an alternative explanation of the findings. The aim is to produce valid and reliable results (Gerrish and Lacey, 2006).

For reality to be measured in quantitative research, it needs to be broken down into parts that can be measured and where results can be reproduced. Immense importance is attached to the accuracy of the instruments developed to measure what is being researched and to consistently reproduce the results. This accuracy allows other researchers to replicate the study. Objectivity is another feature of quantitative research, as it is a strategy used to reduce bias. Randomisation is an example of one method used to achieve objectivity or detachment - whereby the researcher is blinded to which subject receives an intervention or not.

In contrast to the quantitative approach, qualitative research seeks to understand the whole of the human experience and to gain insight into human behaviours. It is a systematic, interactive and subjective approach used to describe life experiences and to give them meaning (Burns and Grove, 2001). Data collected is usually in the form of interviews and observations and are extremely time consuming for both collection and analysis of data; as a result the number of participants in the study is small and no randomisation is required (Morse and Field, 2002).

The nature of nursing phenomena is such that both quantitative and qualitative methods have a valuable contribution to make. A paradigm comes from the Greek word "pattern" and when applied to science describes the way society views the world. It is a set of propositions that explain how the world is perceived (LoBiondo- Wood and Haber, 2006). Nursing research is mainly conducted within two broad paradigms: The naturalistic or interpretive paradigm, and the positivist paradigm (LoBiondo- Wood and Haber, 2006).

3.3.2 The Naturalistic Paradigm

The naturalistic paradigm represents an alternative system for conducting disciplined research in the field of nursing and is closely aligned to the qualitative method of research. In the naturalistic paradigm the reality is not fixed, it is a construction of the individual participating in the research; there are multiple interpretations of reality that exist in people's minds. The naturalistic paradigm deals with the issue of human complexity by exploring it directly. It aims to understand the human experience as it is lived, through the collection and analysis of narrative, subjective material. The voices and interpretations of those under study are key to understanding the phenomenon of interest and subjective interactions are the primary way to access them. The findings from a naturalistic inquiry are the product of the interaction between the researcher and the participant (Polit *et al.* 2000).

3.3.3 The Positivist Paradigm

The positivist paradigm is rooted in 19th century thought guided by philosophers such as Newton and Locke and remains a dominant force in scientific research. The fundamental assumption of the positivist paradigm is that the objective reality exists and can be studied and known. Positivists believe that phenomena are not random events, within the positivist paradigm the researchers' activity is directed at understanding the underlying causes of natural phenomena (Polit *et al.* 2000). As a

result of the objective reality positivist researchers aim to be as objective in their pursuit of knowledge as possible, they hold their personal beliefs and biases in check during their research. The positivist paradigm calls for orderly disciplined procedures to test the researchers ideas about the nature of the phenomena studied. Quantitative research methods are thus associated with the positivist paradigm.

This study sets out to examine the impact of a nursing education intervention on the compliance of patients with asthma in using an inhaler, by measuring the patient's inhaler technique before and after an education programme. The research question relates to the measurement of patient behaviour before and after an education programme. Studies that seek to measure human behaviour are addressed through quantitative research methods - thus the positivist paradigm underpins this study.

3.4 Rationale for adopting a Quantitative Method

The use of quantitative research allows for objective measurement which can be empirically observed, recorded and verified - therefore the degree of error and bias is greatly reduced. By using objective measurements the researcher is distanced from the phenomena and therefore it is the research tools that do the measuring and not the researcher.

Nurses are accountable for their practice and need to base their practice on evidence. It is crucial for nurses to evaluate their practice to see if their care delivery is informed and based on an ethos of evidence, which in turn will make their service more efficient and cost effective. For this piece of research the writer deemed that a quantitative method was appropriate. This method was chosen for two reasons. Firstly, observational and recording procedures were chosen to complete data collection; secondly, the writer set out to explore the effectiveness of a nurse-led education programme by comparing the outcome measures pre- and post-intervention.

3.5 Quantitative Research Design and Methods

In this section the writer will discuss the research designs used for quantitative studies - in particular the design used for this study.

3.5.1 Quantitative Research Design

Within quantitative research there are three different designs which can be used to carry out this process. These designs are as follows; experimental, quasi experimental and non-experimental. In experimental and quasi experimental designs the researcher seeks to bring about the desired effect and does not passively observe customary patient care (LoBiondo-Wood and Haber, 2006).

True experimental design - commonly known as a randomised clinical trial - is the best design and is the gold standard for providing information about cause-and-effect relationships. These experiments have three properties: randomisation, control and manipulation. This design out-rules other explanations for the phenomenon. Most research in nursing is not true experimental.

Quasi-experimental design also tests cause-and-effect relationships; however one or more components of the true experiment are missing. It has an intervention, no randomisation and may or may not have a control group. Because full experimental control is not possible, confidence that the findings were as a result of the intervention (and not the extraneous variables), is weakened. However there are numerous approaches that can strengthen the validity of the experiment (LoBiondo-Wood and Haber, 2006).

There are several types of Quasi-experimental Designs:

- ***Non-equivalent control group design***: this design is similar to the true experiment except the subjects are not randomly assigned to groups. Both the experimental and control groups have a pre- and post-test design, but only the experimental group receive the intervention.
- ***After-only non-equivalent control group design***: Randomization is not used to assign subjects to groups. It is assumed that the two groups are

comparable. Therefore there is no pre-test; the experimental group only receive the intervention, and data are collected on both groups post intervention.

- ***One group (pretest-posttest) design***: this design is used when there is only one group available for study. Data are collected before and after an experimental intervention on one group of subjects.
- ***Time series design***: this design is used by researchers when only one group is available to study over a longer period of time. In this design data are collected multiple times before the intervention to establish a baseline point of reference. After the intervention is introduced data are collected multiple times to determine the change from the baseline (LoBiondo-Wood and Haber, 2006, Polit *et al.* 2000).

This study is concerned with evaluating the effectiveness of a nursing education intervention on the compliance of patients with asthma in using an inhaler, by measuring the patient's inhaler technique before and after an education programme. Thus a positive paradigm, quantitative study, engaging a quasi-experimental pre-test and post-test design was adopted. No controls were used as it was believed that it was unethical to withhold asthma education and monitoring to any asthmatic patient who agreed to participate in the study. Also, inhaler technique education is seen as being advantageous to the patients.

3.5.2 Quantitative Research Methods

Methods are the steps, procedures and strategies for gathering and analysing the data in a research investigation (Polit *et al.* 2000). Four methods of quantitative data collection have been devised. These are; cross sectional, longitudinal, retrospective and prospective.

A cross sectional study is based on observation of different stages or developmental group at a certain point of time for the purpose of inferring trends over time. A longitudinal study is designed to collect data at more than one point. A retrospective study begins with the occurrence of the dependant variable in the present and then links this effect to some cause in the past. A prospective study begins with an examination of presumed causes and then goes forward in time to observe presumed effects (Polit et al. 2000).

For the purpose of this study, a single-centre, prospective, longitudinal study design was chosen, as the data was collected at three points of the study. These were: on joining the study, at the end of three months, and three months after the post-stage measurement. Methodologies employed include the use of questionnaires, patient assessment and review of charts.

3.6 Determination of Overall Study Design / Method.

The design selected by the writer for the study was quasi-experimental, as the object of the study was to ascertain how effective a nurse education intervention is on the compliance of patients with asthma using an inhaler, by measuring the patient's inhaler technique before and after an education programme.

For this study an inhaler technique education intervention was put into operation with regular (i.e. 4 weekly) follow-up.

A longitudinal method was employed to allow observations and recording of data at three points pre- and post-interventions throughout the study. It was contemplated that other factors could influence the outcome measures being observed within this study, for example the participant being unwell when data was being collected. These factors were recorded and analysed with the study results.

No controls were used due to ethical considerations.

Thus a positive paradigm, quantitative study, engaging a quasi-experimental pre-test and post-test design was considered most appropriate for this particular study.

3.7 Population, Sample and Sampling.

3.7.1 Population

Population is defined as the entire collection of cases that meet a specified set of criteria (Polit *et al.* 2000). LoBiondo-Wood and Haber (2006) define population as a well-defined set that has certain specified properties. Gerrish and Lacey (2006) describe a population as all possible participants that could be included in a sample. It is vital that a population includes all those who could potentially take part in the study (Parahoo, 2006), if it is to be representative of the population under being researched.

The population for this specific study consisted of patients who had asthma and were already participating in a medically focused study. Following ethical approval (Appendix 2), a process for identifying suitable participants was established. The writer encountered patients with asthma in the medically focused clinical study and potentially suitable patients were screened for inclusion in this research study.

3.7.2 Sample and Sampling

Parahoo (2006) describes the sample as a portion of people from the defined population from which the researcher wishes to obtain the data. The purpose of the sample is to increase the efficiency of a research study (LoBiondo-Wood and Haber, 2006).

It is not feasible or necessary to interview every member of the population to elicit their experience; rather a sample of the population can be chosen (Parahoo, 2006). LoBiondo-Wood and Haber (2006) state that sampling is a process of selecting a portion of a designated population; this then is representative of the entire population. A sample is a set of elements that make up the population (Polit *et al.* (2000), LoBiondo-Wood and Haber (2006).

The sampling methods commonly used by quantitative researchers are convenience sampling, quota sampling and purposive sampling. Sampling is grouped into two groups: *probability and non-probability sampling.*

- With **probability sampling** each element of the population will be included in the sample and researchers can have confidence that it is representative of the population.

- With **non-probability sampling,** elements are selected by non-random methods; therefore every element does not have a chance for inclusion.

As this is not a randomised controlled trial (RCT) and adopts a pre post-test design, no formal sample size calculations were performed. A subset of the patients attending the Out Patients Department had already been selected for the medical study using purposive sampling, however convenience sampling was utilised in this study. This type of sampling was used as patients were easily accessible from the medically focused clinical study. The writer's objective was to recruit a subset of the patients in the clinical study. The number of patients was limited in terms of time allocated to the study and the time scale allowed for data collection within the context of an MSc. The primary restriction (apart from numbers of patients attending the Out Patient Department) was one of time as this is a research study for an MSc Degree Programme.

The writer is aware that using non-probability sampling leaves this study less representative of the whole population of asthmatic patients; however despite the limited time window and resources available, the largest sample available was used. The writer intended recruiting 20 patients to this study and therefore targeted all new patients referred to the medical clinical study already in situ over a 6 month period. As there was also a risk of biases with non-probability convenience sampling, the writer ensured homogeneity of the sample by using a set of inclusion and exclusion criteria to identify suitable participants. The writer is also aware that a larger sample size would have been more beneficial, and this would be the case in any future follow-on study.

Inclusion Criteria

The inclusion criteria for entry into the study were as follows:

1. Capable of understanding and willing to provide voluntary informed consent before any protocol specific procedures are performed,
2. Clinical diagnosis of asthma (as indicated by documentation of 15% variation in FEVI in Pulmonary Function Test (PFT) within past 5 years),
3. Age 18 years or older at time of consent,
4. Capable of understanding and complying with the requirements of the protocol, including ability to attend for all required visits,
5. Able and willing to take inhaled asthma medication.

3.7.4 Exclusion Criteria

The exclusion criteria for entry into the study were as follows:

1. Current smokers,
2. Have a known significant concurrent medical disease.

3.8 Accessing the Sample Population

The research was conducted in a clinical research centre adjacent to a large Dublin teaching hospital. The participants were already participating in a medically-led academic study. The respiratory consultant conducting the medically-led academic study was approached, personally, requesting access to his patients for participation in this nursing study.

All new patients participating in the medically focused study who corresponded with the inclusion \ exclusion criteria for the writer's research were invited to take

part in the writer's study. They were all given an Information Leaflet and a Consent Form (Appendix 5) which explained the writer's study in detail to them. Each participant had ample time to read the Information Leaflet and Consent Form and to ask any questions of the researcher. If they decided to participate in the study the Consent Form was signed by the participants and the researcher. A copy of the Consent was given to each participant.

3.8.1 Data Collection Methods

The phenomena being investigated by the researcher must be translated into measurable, observable or recordable concepts. The fundamental principle to data collection in quantitative research is that data is collated in a way that is independent of the expectations of the observer and that the data is truly representative of the phenomena (Botti and Endacott, 2005).

Without appropriate data collection methods the validity of research results can be challenged. The success of a study depends on the quality of the data-collection methods. LoBiondo-Wood and Haber (2006) and Polit *et al.* (2000) define data as information systematically collected in the course of a study. Gerrish and Lacey (2006) describe a number of different methods of data collection used in nursing research, including interviews, focus groups, questionnaires, observations and physiological measurement. Parahoo (2006) concurs, but also includes scales to measure knowledge and skills as the main methods of data collection in quantitative research.

For the medically-led study, Patient Demographics were recorded in Case Record Forms that were also used in the writer's study for each patient that participated simultaneously in both studies. The information extracted was:

- Gender,
- Date of Birth,
- Asthma history,
- Peak flow,

- Inhaler use,
- Number of exacerbations in the past year,
- Height and weight, and
- Smoking History.

3.8.2 Observation, Education and Questionnaires

In this study observation, education and the Patient Reported Behaviour (PRB) Questionnaire were utilised to review inhaler technique and competency.

Observation

An observation tool - the Inhaler Proficiency Schedule (IPS) - was designed by the researcher and was validated by both the respiratory consultant and the respiratory nurse specialist. This tool allowed the researcher to record specific observations made while the participant took their inhaler. Any errors in technique were identified on the IPS so that corrective education could be given to the participant by the researcher.

Education

It is necessary for an educator to have formulated a plan or protocol for teaching a skill. By using a step by step education plan it was possible to teach the participant the skills necessary for successful inhaler technique. Adapting a methodology outlined by Ewles and Simnett (1999) the researcher in this study identified the following steps:

Step 1: Identify the skills needed by the participant to perform correct inhaler technique, and then assess the gap between where the participant is now with those skills.

Step 2: Identify the skill gaps and translate these into learning objectives. For this study, an understanding of how the inhaler works and how the drug is delivered by

the inhaler may be necessary. For example - "hold the inhaler in a horizontal position" - this makes sense to the participant when it is explained that the drug may fall out the mouthpiece of the inhaler if it is tilted to one side.

Step 3: Accomplish the learning objectives by giving a practical demonstration. The researcher demonstrates the correct technique to the participant.

Step 4: Evaluate the learning process by testing the skills that the participant has learnt. The researcher asks the participant to demonstrate the procedure/technique as a measure of what they have learned.

To ensure that the researcher's inhaler technique was correct, the researcher was educated in the correct inhaler technique for a DISKUS inhaler by the respiratory nurse specialist. The product literature was also consulted.

As education was delivered to an adult group, the principles of adult learning were applied (Ewles and Simnett 1999). These include recognising that adult learners learn best by being active, by doing and by experiencing. The learning environment must be conducive to this approach. For this study, every participant was seen in a consultation room to allow for privacy and to facilitate good interaction between the researcher and participant. The process of completing the PRB Questionnaire, the IPS and the demonstration of inhaler technique all required active participation.

Adult learners should evaluate their learning on a continuous basis. To this end a "dummy inhaler" was given to each participant to practice their technique. The participants were encouraged to practice their technique at home on the dummy inhaler before using the active inhaler.

This is the routine that the writer followed based on the 4 step plan described above:

- The participant's technique was checked against the IPS,
- The participant was given verbal instruction,
- The researcher demonstrated the correct technique,
- The participant was asked to demonstrate their technique,

- Any errors identified were rectified,
- The participant repeated their demonstration to check they had understood all steps. This process was repeated as necessary until the participant could perform all of the steps correctly,
- At each subsequent visit the assessment and education process was repeated.

Questionnaire

Questionnaires are research instruments most commonly used in surveys. They must be designed to collect specific information that will provide answers to the research question. The questionnaire used in this study (the PRB) was again designed by the researcher and validated by both a respiratory consultant and a respiratory nurse specialist. The participant was asked a series of specific questions in relation to their condition, confidence level with self-administration of their inhaler, and adherence to prescribed frequency of use.

- Questions 1 - 5 required a "yes" or "no" answer.
- Question 6 was to give a reason if the answer to Q5 was "no"
- Question 7 and 8 employed Likert scales.
- Question 9 was a visual analogue scale.

The data chosen by the writer for collection was collected using both objective and subjective measurement tools. The first, second and follow-up assessments involved face-to-face contact with the writer. Participant demographics were taken, and then the participant was asked to demonstrate their inhaler technique, if they were already on the DISKUS inhaler. Those new to the DISKUS inhaler were given training following the education protocol in use of the device. Both groups were then scored for technique using the Inhaler Proficiency Schedule (IPS). The participant was also given the questionnaire to complete.

The participant was given education on entering the study at month 0 (visit 1). The participant was educated monthly while attending the medical-led study. The education programme was developed through review of best practice and the finding of the pre-test phase.

After a period of three months - on visit 2 - the pre-test process was repeated. The participants were asked to demonstrate their use of the inhaler and the IPS was again used to record the participants' proficiency. The same questions asked in the pre-test were asked again during this stage.

The process was to be repeated one more time, three months later in a post-test follow-up visit. The participants received no education between visit 2 and the follow-up visit.

3.9 Validity and Reliability

3.9.1 Rigour

Rigour refers to the strength of the research design, that all procedures have been adhered to accurately and consistently, and that the researcher can be confident that all conclusions drawn are dependable. The quality of the research will be judged by how it has been carried out. There are two main components that affect the quality of research. These are: validity and reliability.

3.9.2 Validity

Validity is defined as the degree to which an instrument measures what it is intended to measure (Polit *et al.* 2000, LoBiondo-Wood and Haber 2006).

Before engaging in a study, the researcher should measure the validity of all the instruments that are to be used in the study. No test is valid without being reliable. The kind of validity information gathered depends on the aim of a measurement. In

quantitative research, validity can be ensured by careful sampling, appropriate instrumentation and appropriate statistical analysis of data. There are three kinds of validity that are used according to the information provided and the purpose of the researcher. These are: content, criterion-related and construct validity.

For the purpose of this study the researcher concentrated on face validity, which is a subtype of content validity. Face validity refers to whether the instrument looks as though it is measuring the appropriate construct.

For this study two measuring instruments were developed.

- The Inhaler proficiency Schedule (IPS) was adapted from a standard protocol using a ten point scoring system developed and supported by the inhaler manufacturing companies. This IPS was validated by the respiratory consultant and nurse specialist.
- The Patient Reported Behaviour (PRB) Questionnaire was adapted from questionnaires used in previous studies and again validated by the respiratory consultant and nurse specialist.

3.9.3 Reliability

Reliability is defined by LoBiondo-Wood and Haber (2006) as the constancy of a measuring instrument, while Polit *et al.* (2000) state that it is the degree of consistency or accuracy with which an instrument measures the attribute it is designed to measure. Watson *et al.* (2008) describe reliability as the extent to which a tool will make the same measurement each time it is used.

The three main attributes of reliability are stability, homogeneity and equivalence.

- ***Stability*** refers to an instrument's ability to reproduce results repeatedly; it can be affected when more than one researcher is involved.
- The ***homogeneity*** of an instrument refers to all the items in a tool that measure the same concept.

- An instrument is said to exhibit ***equivalence*** if the tool produces the same results when equivalent instruments or procedures are used (LoBiondo-Wood and Haber 2006).

3.10 Pilot Study

In quantitative research, data collected must be discarded if changes have to be made to the research design, sampling plan or data collection instruments after the study is underway. For this reason, some researchers will carry out an initial Pilot Study. A Pilot Study takes the form of a small-scale trial of the research methods. It will highlight any problems with the process of collecting data from the participants, which can then be addressed prior to commencing the main study (Polit *et al.* 2000).

There are two steps to performing a pilot study. The first step tests the measurement tool. The second step tests the feasibility of the study as a whole. The writer conducted the first step of a pilot study on 2 participants to test the IPS and questionnaire. Due to time constraints the second part could not be performed.

The two Pilot Study participants were asked to demonstrate their inhaler technique in order for the writer to evaluate the IPS. They were also asked to complete the PRB questionnaire. The participants were asked if they found any questions difficult to understand or read. One participant reported that on the visual analogue scale, the number 8 was repeated and that the number 9 omitted. The PRB questionnaire was subsequently amended.

The writer found the pilot study very helpful as she was able to practice her data collection skills.

3.11 Data Analysis

The purpose of data analysis is to organise, provide structure to, and elicit meaning from research data. Quantitative research involves the collection of numerical data. To understand this, numbers are summarised into a format that is understandable - this is descriptive statistics. When data are described, inferential statistics are applied so that full understanding of the data can be achieved (Watson *et al.* 2008).

Quantitative data is analysed by performing descriptive and inferential statistical techniques. Descriptive statistics allow the researcher to summarise or describe the data. Inferential statistics permit assumptions on whether relationships observed in a sample are likely to occur in the population. Quantitative research data is stored and analysed in numerical format. Some of the data is captured directly as numbers (e.g. age), while other information (e.g. gender) can be changed into numerical format. Scales which have a logical order (e.g. levels of pain) can also be coded numerically. Some numerical data can be mathematically calculated (added, subtracted etc.), while it would not make sense to do so with other numerical data.

The different ways in which numbers can be used is referred to as levels of measurement (Watson *et al.* 2008). There are four different levels of measurement, and these are (in order of increasing precision):

- nominal,
- ordinal,
- interval, and
- ratio.

How these can be used to define different data properties is summarised in Table 3 below (Watson *et al.* 2008).

Table 3. Different levels of measurement and their properties

	Nominal	*Ordinal*	*Interval*	*Ratio*
Different Categories	Yes	Yes	Yes	Yes
Categories can be ranked		Yes	Yes	Yes
Equal distances between categories			Yes	Yes
Fixed Zero				Yes

Once quantitative data is collected, it is initially interpreted using descriptive terms. It can be presented in table or chart form, which can be useful for displaying the raw data, but the frequency of occurrence of the information still needs to be ordered and grouped. Charts have an immediate visual impact; bar-charts and pie charts use a lower level of measurement, while a histogram has two scaled variable axes and can be used for interval or ratio levels of measurement.

Inferential statistics is concerned with applying conclusions to something wider than the observation at hand due to some properties of that observation (Watson *et al.* 2008). It also allows us to do this with a level of confidence or certainty. Because it is very rare in practice to have access to the whole population for a study, smaller samples in conjunction with inferential statistics are used to draw conclusions about the population as a whole. The most important thing to remember about confidence level is that, the greater the confidence level we wish to express, the wider will be the corresponding range for the mean of the data under consideration.

Another key concept in inferential statistics is that of statistical significance – this is a measure of the probability that the outcome being measured is a result of the

phenomenon being measured, rather than a chance outcome. The use of statistical significance means that what are known as Type I errors are avoided, and that statistical significance is not applied to a result too readily (Watson *et al.* 2006).

The design selected by the writer for the study was quasi-experimental, incorporating pre- and post- test components, as the object of the study was to ascertain how effective a nurse education intervention is on the compliance of patients with asthma using an inhaler, by measuring the patient's inhaler technique before and after an education programme and to measure if this education is sustained over a three month period.

For this piece of research the writer deemed that a quantitative method was appropriate. This method was chosen for two reasons. Firstly, observational and recording procedures were chosen to complete data collection; all data collected on the Inhaler Proficiency Schedule and most of the data collected on the Patient Reported Behaviour Questionnaire could be translated in to a basis for numerical scoring. Secondly, the writer set out to explore the effectiveness of a nurse-led education programme by comparing the outcome measures pre- and post-intervention.

Quantitative data needs to be properly recorded and stored for initial validation and later for analysis purposes. LoBiondo-Wood and Haber (2006) highlight the need for a systematic plan when entering data into a computer. The first step in the analysis of this study was the coding of all the variables into numeric form. Pallant (2008) outlines the creation of a codebook to define and label each variable and assign numbers to each possible response on the data collection tool. Using the codebook as a reference, all the data from the study was entered using PASW Version 18 into a password-protected computer. Prior analysis of the data file and cleaning of the data was completed by ensuring the scores of each variable were checked and within range.

3.12 Ethical Considerations

The Declaration of Helsinki (1964) which was revised in 2008, states that the interest of science and society must never take a priority over the interest of patients. Following this declaration, ethical principles were set up to guide researchers. The Department of Health and Children (2003) states that nurses and midwives must acknowledge that all research must comply with, and adhere to, the principles associated with the conduct of ethically sound research, whereby the rights of patients and participants are protected at all times.

In Ireland, An Bord Altranais (2007) Code of Professional Conduct refers to the issue of nursing research by advising nurses of their duty to establish that research studies have been sanctioned by the appropriate body, and also to ensure the rights of the patients are protected at all times. In 2007 these guidelines were reviewed and new guidelines were developed to guide nurse and midwifes regarding the ethical conduct of nursing and midwifery in research.

3.13 Study Approval

Therefore before conducting a study, ethical approval is required. As all participants in this study were patients of the local hospital, an application for approval of the study was submitted to the local Ethics Committee. The application to the Ethics Committee involved the submission of:

- a copy of the completed Application Form,
- a copy of the Research Proposal,
- the Questionnaire and IPS,
- the Patient Information Leaflet and Consent Forms, and
- a cover letter.

An electronic copy of these documents was also requested.

The Ethics Committee meeting was held on 10th December 2010, one month after the application was submitted. One week after the meeting the writer received a

letter from the Ethics Committee, indicating approval to conduct the study pending clarification of the following issues:

1. Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.
2. Please give a brief justification of sample size and details of the sample size calculation (including minimum clinically important difference).
3. The Committee asks if it is intended to exclude pregnant women from this study.
4. The Committee notes that there is a larger study taking place involving the same participants. The Committee seeks assurances that this new study will not negatively impact / endanger the results of the on-going study, and that the patient visits (4 visits in all) can be aligned to other visits subjects are having as part of the larger study.
5. The Committee notes that a number of irrelevant questions haven't been deleted in Section C3 and C4. This also applies to Question D4 (b) which needs to be deleted.
6. The Committee requests the rephrasing of the following sentence on page 2 of the Information Leaflet: 'Only limited people involved in this study will have access to this information.

In a letter of reply the writer dealt with the Ethics Committee's requests for clarification as follows:

1. Data will be collected using the Questionnaire and the Inhaler Proficiency Schedule (as validated by a Respiratory Nurse Specialist and Respiratory

Consultant). Data from visit 4 and 5 will be compared with base line data collected at visit 1. A scoring system will be applied to the IPS data to allow numerical comparison of the collected data. Descriptive analysis will also be presented, reporting differences in patient behaviour compared to best practice and differences in patient behaviour pre and post-test. The Statistical Package for Social Sciences (SPSS) will be used for data entry and analysis.

2. As this is not an RCT and adopts a pre post-test design, no formal sample size calculations were performed. However, on average 30 asthma patients are seen per month in the Out Patient Department, of whom it is hoped to recruit 60% to 80% for the main study. The researcher plans to recruit a subset of these patients but is limited in terms of time allocated to the study and the time scale allowed for data collection within the context of an MSc. The primary restriction (apart from numbers of patients attending the Out Patient Department) is one of time as this is a research study for an MSc Degree Programme.

3. It is intended to exclude pregnant women as they will be excluded from the larger study as pregnancy can affect asthma both positively and negatively.

4. This new study will not negatively impact on the larger study as the intervention at visit one is observational only, and all study visits will be aligned to the other visits subjects are having as part of the larger study.

5. The irrelevant questions have been deleted.

6. The sentence has been deleted on the PIL as it was not necessary.

After the responses were submitted, the writer received notification of full approval to conduct the study on the 6th January 2011 (Appendix 2).

3.13.1 Informed Consent

Prior to conducting research it is essential to obtain informed consent from all participants. Treacy and Hyde (1999) point out that it is not enough to simply obtain consent from the participant to take part, but that researchers must ensure that participants fully understand what they have agreed to do. In this study a full and proper explanation of the study was given to all participants in the form of a Patient Information Leaflet (PIL), in language that is easily understood, informing the patient of all pertinent aspects of the study including the ethical approval. They were given ample time to consider their participation and to ask questions. Upon deciding to participate, the written informed consent was then signed and personally dated by both the patient and the writer who conducted the informed consent discussion. A copy of the signed PIL and consent was given to the patient.

3.13.2 Beneficence / Non- maleficence / Confidentiality

Nurse researchers must safeguard their participants' rights and safety, thus, the ethical principles of beneficence, non-maleficence, and confidentiality, should be adhered to.

3.13.3 Beneficence

Beneficence is active; it is the obligation to act to benefit others and to maximise possible benefits (LoBiondo- Wood and Haber, 2006). Parahoo (2006) comments that research should be conducted with the intent to benefit the participating individual and society in general. In this study the writer sought to explore ways of improving nursing practice for the benefit of patient care and the general public.

One of the key benefits for the participants in this study is that they will receive regular refresher training to ensure that they are using their prescribed inhalers correctly; one of the potential outcomes of the study will be the identification of common errors or faults in use, which can later be incorporated into future education programs for all inhaler users. By carrying out this research, the writer hopes to discover whether this study will improve the health of people with asthma.

It may benefit the participants by improving their understanding of their condition and providing the opportunity for them to learn to use their inhaler more effectively. The study promotes a model of self-care which is significantly important in chronic disease management. The findings will also make a valuable contribution to the body of nursing knowledge.

3.13.4 Non-maleficence

The ethical principal of non-maleficence is derived from the concept that one should not inflict evil or harm; this is a passive concept, as opposed to beneficence, which is active. Nurse researchers have an ethical duty to balance potential benefits against potential risks, therefore minimizing risk to safeguard and protect participants (An Bord Altranais, 2007).

Though there is no harm foreseen for the participants in this study, the writer is aware that data confidentiality, data protection and data storage fall under the principle of non-maleficence. For this reason, patient confidentiality during the data collection process will be maintained by ensuring that no data on any unique patient identifiers or site identifiers (such as name, address, telephone numbers etc.) are obtained. The patient's name is retained only on the consent forms kept by the writer, and on patient tracking logs kept at the hospital. The questionnaires and IPS will be kept for at least 3 years after termination of the study in a locked storage cabinet, after which paper data will be confidentially shredded and electronic data will be deleted.

3.14 Summary

This chapter has outlined the research methodology and research design that has been implemented to evaluate the effectiveness of a nurse education intervention on the compliance of patients with asthma in using an inhaler, by measuring the patient's inhaler technique before and after an education programme. The explanation for a positivist approach with a quantitative methodology was also discussed.

Numerical formats and the different levels of measurement, along with their properties were reviewed. Options for data presentation, including tables and charts were examined, although the very detailed analysis of the collected data was achieved through the use of SPSS Version 18. The concepts of inferential statistics and statistical significance were also investigated.

Sample selection and access to the population was highlighted. A PRB questionnaire and IPS were developed and tested for reliability and validity and utilised as measuring tools. A detailed account of how data collection was carried out was also provided. Ethical considerations were outlined as a core consideration in the conduct of this study.

The data collected on all the participants was related to age, gender, years of asthma diagnosis, peak flow, number of asthma exacerbations in the past 3 months, steroid use in the past year, smoking history and inhaler use. Data were also collected on inhaler proficiency and patient behaviour in relation to their inhaler

Data collection was carried out by assessing the patients' inhaler technique using an Inhaler Proficiency Schedule (IPS) and through the patients' completion of the Patient Reported Behaviour (PRB) Questionnaire. This process was repeated over two subsequent visits.

The participants were enrolled over a six month period, from January 2011 to June 2011; as each person participated in the study for six months, the effective data collection period ran from January 2011 to December 2011.

Chapter Four – Presentation of the findings

4.0 Introduction

This study set out to explore the impact of a nursing education intervention on the compliance of patients with asthma in using an inhaler, and to consider the implications of the findings on the role and function of nurses.

This chapter will outline the study findings, present the results obtained pre-intervention and post-intervention, and give a comparison of both sets of results. Descriptive data was reported and where possible inferential statistics were used to explore the difference in all the variables pre and post intervention. The results obtained from the study are reported under the following headings:

Participant Demographics

- Age, Gender,
- Height, weight and BMI,
- Smoking History & Smoking Pack Years.

Asthma Status

- Years of diagnosis,
- Number of exacerbations in past year,
- Number of visits to GP in previous 3 months,
- Inhaler Use,
- Years on Steroids / years on DISKUS inhaler.

Inhaler Proficiency Schedule

Peak Flow

The results are presented in text and table format with statistical analysis included when deemed appropriate.

4.1 Participant Demographics

Twenty one asthmatic patients (as per GINA guidelines 2008) were approached about participating in the study. Following discussions with each patient and the presentation of a Patient Information Leaflet regarding the study, all twenty one patients agreed to partake in the study. However, after visit one, two patients decided to withdraw from the study and one patient missed their middle visit due to a pre-planned holiday (on the patient's part).

4.1.1 Age & Gender

The total number of participants was twenty one (n=21). All of the participants were between 20 years of age and 67 years of age with a mean age of 40.95 years ± 14.3 years.

Ten males (n=10) with a mean age of 42.3 years ± 13.5 years and eleven females (n=11) with a mean age of 39.7 years ± 15.5 years participated in the study.

Tests for normality, as presented in Table 4, indicate that the distribution of participant population ages is reasonably normal (Kolmogorov-Smirnov Sig. value is > 0.05).

Table 4. Participant Population ages - Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	Df	Sig.
Age of Participant	.115	21	.200*	.953	21	.394

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance

4.1.2 Height and Weight and BMI

The height and weight of all but one participant was recorded on their first visit. This information was then used to calculate the BMI for each participant.

The male participants (n=10) had a mean BMI of 26.87 ± 3.5 and the female participants (n=10) had a mean BMI of 24.4 ± 3.8. All of the participants had a BMI between 19.55 and 31.92, with a mean BMI of 25.65 ± 3.82.

4.1.3 Smoking History

The participants were asked about their smoking history, to identify those who currently smoke or have smoked in the past. 33% (n=7) of the participants were smokers. 60% (n=6) of male participants were smokers while 9% (n=1) of female participants smoked.

The participants were also asked to clarify for how many years they had been smoking.
Smoking history ranged from 0 to 30 years. For the 6 male smokers, the range was 4 to 30 years; the one female smoker had smoked for 10 years.

4.1.4 Smoking Pack Years

A "pack year" is a way of measuring the amount an individual has smoked over a long period of time. This is calculated by multiplying the number of packets of cigarettes smoked per day by the number of years the person has smoked.

Number of "pack years" = (number of cigarettes smoked per day multiplied by the number of years the individual has been smoking) / 20.

In this study, "Pack years" for the smokers varied from 0.60 years to 27 years. The mean "pack years" for all smokers was years 8.36 years, with a standard deviation of 9.02 years.

4.2 Asthma Status:

Asthma status is examined and discussed under headings to cover: years of diagnosis; DISKUS Inhaler use; steroid use and exacerbations in the past year; and number of visits to GP in previous 3 months.

4.2.1 Years of Asthma Diagnosis

All of the participants were between 1 year and 40 years of asthma diagnosis with mean years of asthma diagnosis of 17.3 years ± 12.4 years.

The mean years of asthma diagnosis for male participants (n=10) was 14.6 years ± 12.7 years. Female participants (n=11) had a mean years of asthma diagnosis of 19.7 years ± 12.3 years.

Tests for normality, as presented in Table 5, indicate that the distribution of years of asthma diagnosis is reasonably normal (Kolmogorov-Smirnov Sig. value is > 0.05).

Table 5. Years of asthma diagnosis - Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	Df	Sig.
Years of Asthma Diagnosis	.145	21	.200*	.924	21	.103

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

4.2.2 DISKUS inhaler Use

All of the participants were asked about their inhaler history i.e. whether they were newly prescribed DISKUS inhaler or if they had been on it previously. Male participants (n=10) had a mean years of DISKUS inhaler use of 1.0 years ± 2.10 years. Female participants (n=11) had a mean years of DISKUS inhaler use of 4.3 years ± 4.5 years.

All of the participants were between 0 years of DISKUS inhaler use and 10 years of inhaler use with mean years of DISKUS inhaler use of 2.7 years ± 3.8 years.

It is noted that 52% (n=11) of the original 21 participants had not previously been on DISKUS inhaler, while 48% (n=10) of the participants had previously been prescribed DISKUS inhaler. This gender split and prior DISKUS experience is summarised in Figure 1.

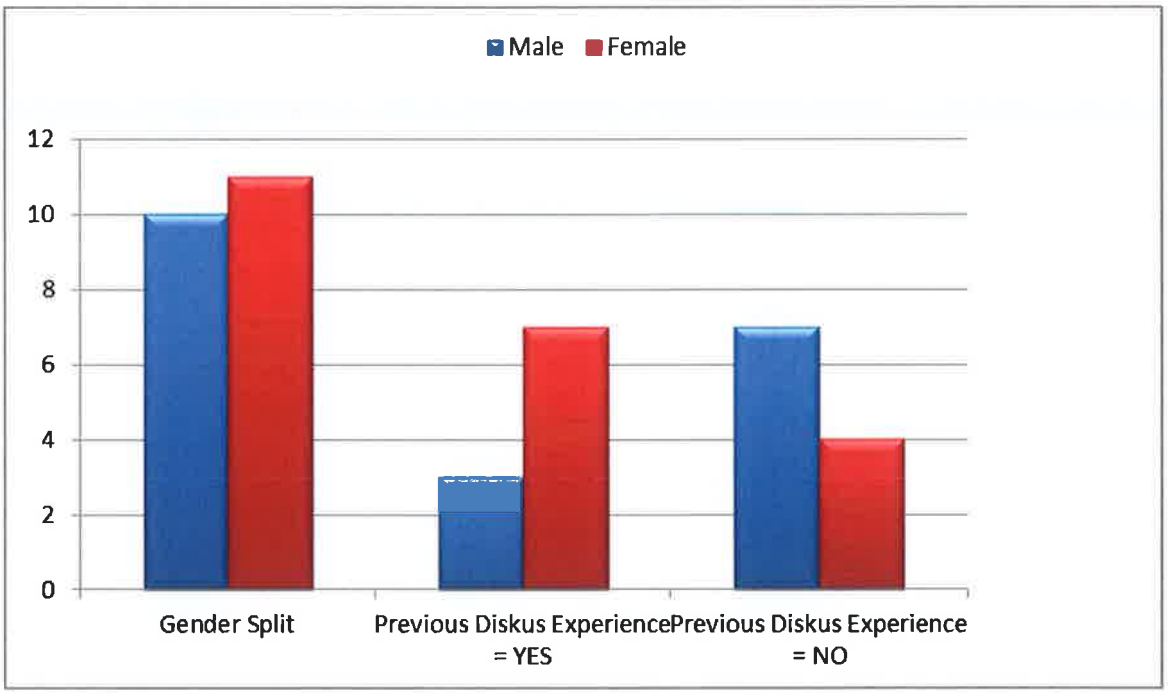


Figure 4. Original 21 Participants – Previous DISKUS experience by Gender

Looking at the 17 participants who completed all visits, it is noted that 59% (n=10) of the participants had not previously been on DISKUS inhaler while 41% (n=7) of the participants had previously been prescribed DISKUS inhaler. Figure 5 summarises the overall previous DISKUS experience for the two views of the patient population.

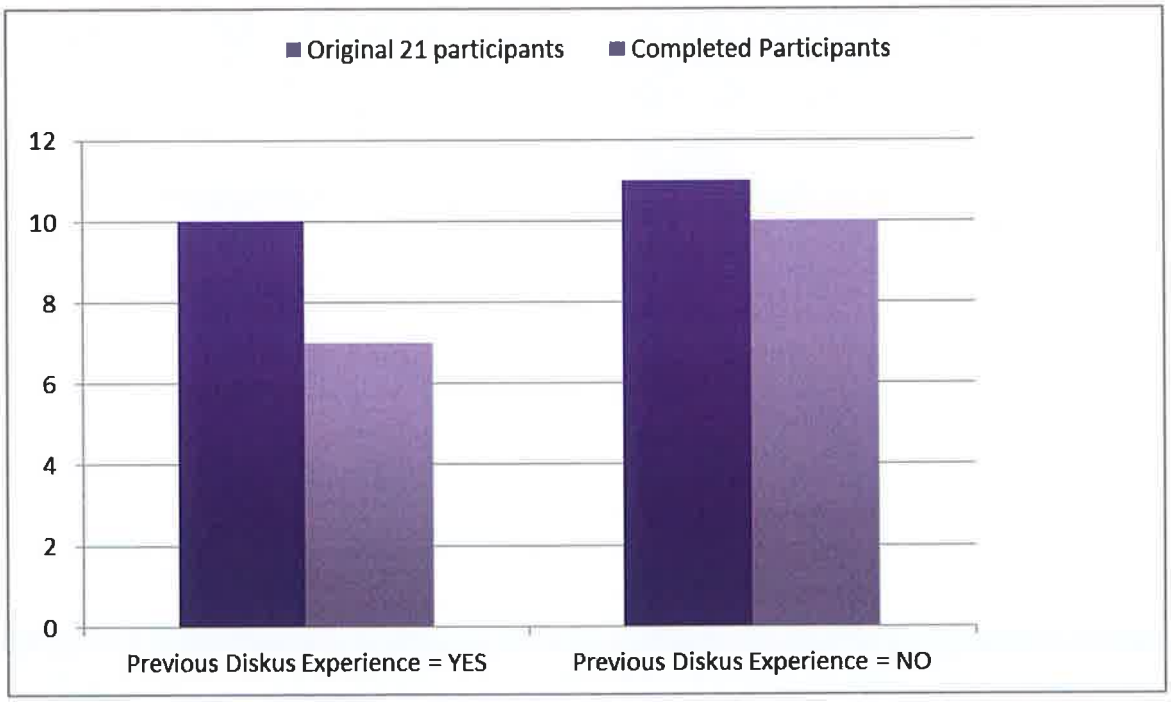


Figure 5. Previous DISKUS experience: original 21 participants vs. 17 completed participants.

The data on years of DISKUS inhaler use was tested for normality (Table 6 below) and the result suggests violation of the assumption for normality. (Kolmogorov-Smirnov Sig. value is < 0.05). While reported use ranges from 0 to 12 years, the usage data is skewed to the range 0 to 6 years.

Table 6. Years of DISKUS inhaler use - Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	Df	Sig.
Years on DISKUS inhaler	.359	21	.000	.709	21	.000

a. Lilliefors Significance Correction

4.2.3 Steroid use in the last year

On visit 1, all 21 participants were asked about their steroid history, specifically whether they had been prescribed steroids in the last year. The number of instances of reported use varied from 0 to 9. For males the reported instances varied from 0 to 6; for females the reported instances varied from 0 to 9. This information is summarised in Figure 6.

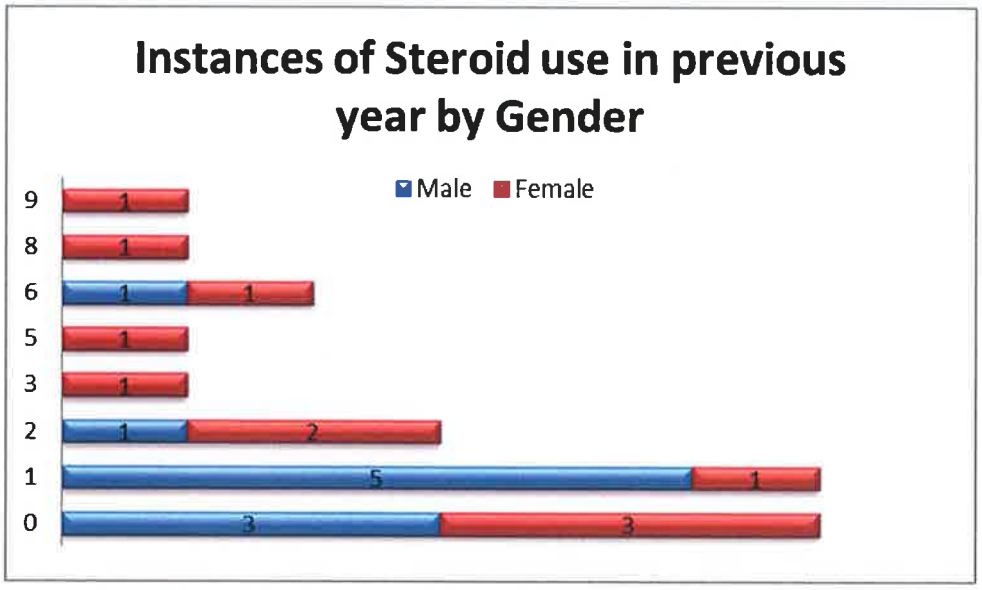


Figure 6. Instances of Steroid use in previous year, by Gender.

71% of participants (n=15) had reported steroid use in the previous year. 70% of males (n=7) had reported use; 73% of females (n=8) had reported steroid use in the previous year.

29% of participants (n=6) had no reported steroid use in the previous year. 30% of males (n=3) had no reported use; 27% of females (n=3) had no reported use.

4.2.4 Asthma exacerbations in last year

An asthma exacerbation was verified as being a change in the participant's asthma status that required an increase of medication or other medication that they did not utilise on a daily basis. The number of asthma exacerbations that each participant encountered for the year prior to participation in the study was documented. Self-reporting was used to record exacerbations in addition to data extracted from their medical notes - not all exacerbations would be recorded in participant notes, as they may also have attended their GP. This information is summarised in Figure 7.

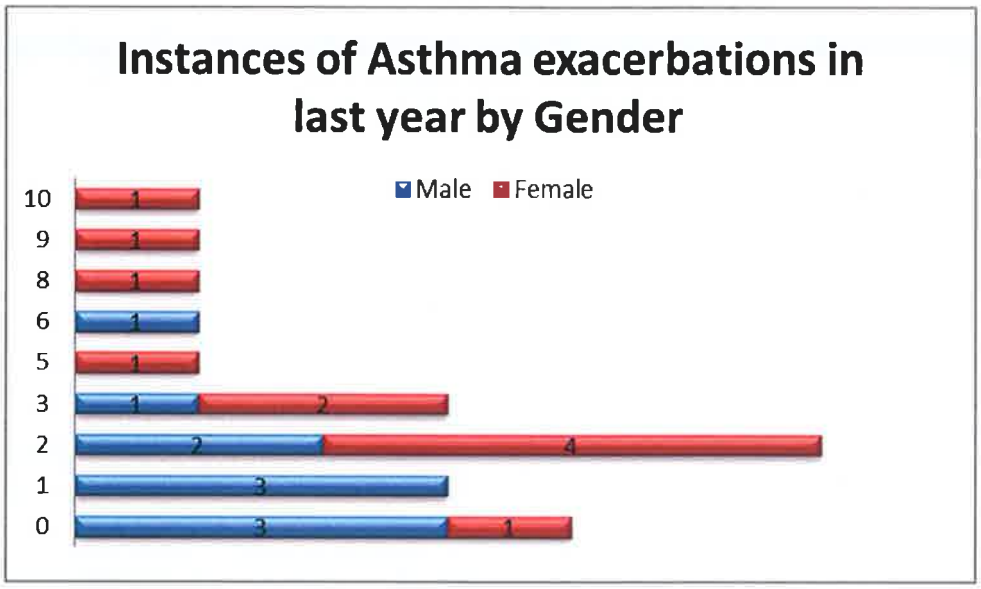


Figure 7. Instances of Asthma exacerbations in last year, by Gender.

In this study, 81% of participants (n=17) had at least one asthma exacerbation in the year prior to entering the study. The number of reported exacerbations ranged from one to ten incidents.

70% of male participants reported at least one exacerbation, with a range from 1 to 6 incidents. 91% of female participants reported at least one exacerbation, with a range from 1 to 10 incidents.

4.2.5 Visits to GP for Asthma in previous 3 months

At the follow up visit, which took place 6 months after commencing the study, participants were asked if they had visited their GP for their asthma in the previous 3 months. Five participants (n=5) had visited their GP. The number of visits by these participants to their GP ranged from 1 to 3. Two male participants (n=2) had visited their GP (each on two occasions); three female participants (n=3) had visited their GP (for one and 3 visits). This information is summarised in Figure 8.

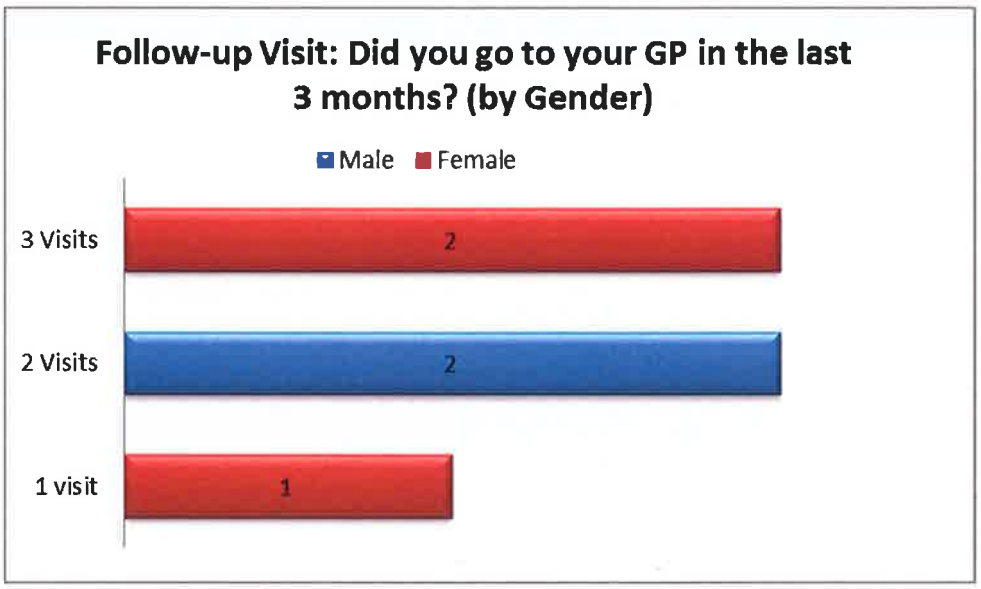


Figure 8. Instances of visits to GP in last 3 months, by Gender.

Three of these participants (n=3) were prescribed steroids as a result of these visits. 2 participants were prescribed steroids at each visit (one visit and two visits respectively); the third participant was prescribed steroids at one of her three visits. All three participants also had their use of their reliever medication increased as a result of the GP visits.

4.3 Overview of the Inhaler Proficiency Schedule Results

A total of three observations of participant inhaler proficiency have been completed through the study.

During visit 1, visit 2 and the follow-up visit, the participant demonstrates their inhaler technique and this is observed and scored against the Ten Step Inhaler Proficiency Schedule (IPS). Three sets of observations \ scores are therefore obtained for each participant for each step of the IPS. While a total of 21 participants entered the trial, three participants (participant ID 7, 9, 13) did not complete all visits, while one participant (participant ID 17) had their medication \ inhaler changed prior to the follow-up visit, so the statistical analysis of the IPS data is looked at for both the complete and incomplete participant pools, as appropriate.

4.3.1 Explanation of IPS Scoring

Each question on the Inhaler Proficiency Schedule has either a YES or NO answer. For analysis purposes, each YES is scored as 1and each NO is scored as zero. As there are 10 questions on the IPS, a participant can score, per visit, a minimum of 0 (for incorrect completion of each of the ten steps) up to a maximum of 10 (for correct completion of all ten steps).

As each participant also completes the IPS on three visits, each question per participant can score a minimum of 0 (for incorrect completion of that step on each of the three visits) up to a maximum of 3 (for correct completion of that step on each of the three visits).

4.3.2 Analysis of the scoring for each question on the IPS

On visit 1, all 21 participants were scored for inhaler technique using the Inhaler Proficiency Schedule. However, only a core of 17 participants completed three sets of IPS visits. Tables 7 & 8 below summarise the IPS scores per visits for each group.

Table 7. Statistical Summary of IPS Scores per visit, for all participants, irrespective of number of IPS visits completed

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Visit 1	21	4.00	10.00	8.6667	1.98326
Visit 2	18	8.00	10.00	9.5556	.61570
Follow-up Visit	18	7.00	10.00	9.4444	.85559

Table 8. Statistical Summary of IPS Scores per visit, for all participants who completed three IPS visits

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Visit 1	17	4.00	10.00	8.4118	2.12305
Visit 2	17	8.00	10.00	9.5294	.62426
Follow-up Visit	17	7.00	10.00	9.4706	.87447

The data shows that the performance of both patient pools is very similar.

Figure 9 below illustrates the performance of the original 21participants for each question on the IPS on visit 1, as well as that of the core 17 participants on visit 1. It

shows the extent to which each step of the IPS was completed by the participant pool. The figure is presented in increasing % completion – tasks least well completed appear at the top, moving to tasks best completed at the bottom.

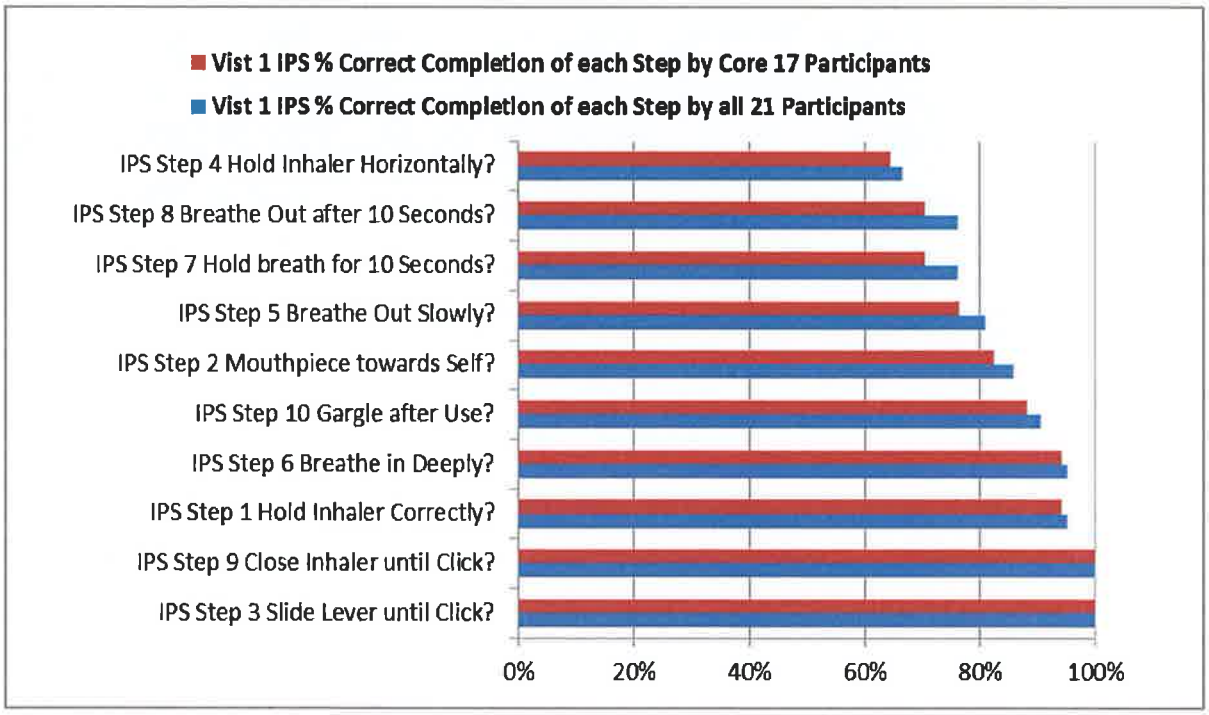


Figure 9. Visit 1 IPS % correct completion of each step.

Again, the data shows that the core group and the total original enrolled pool have similar performance results overall on visit 1. For the purposes of this study, the detailed analysis of IPS scores across all 3 visits is focused on the core pool of 17 participants that completed three IPS scoring visits.

Figure 10 below summarises the performance of the 17 core participants for each question on the IPS across all visits. A score of 3 reflects perfect performance of each step across the three visits.

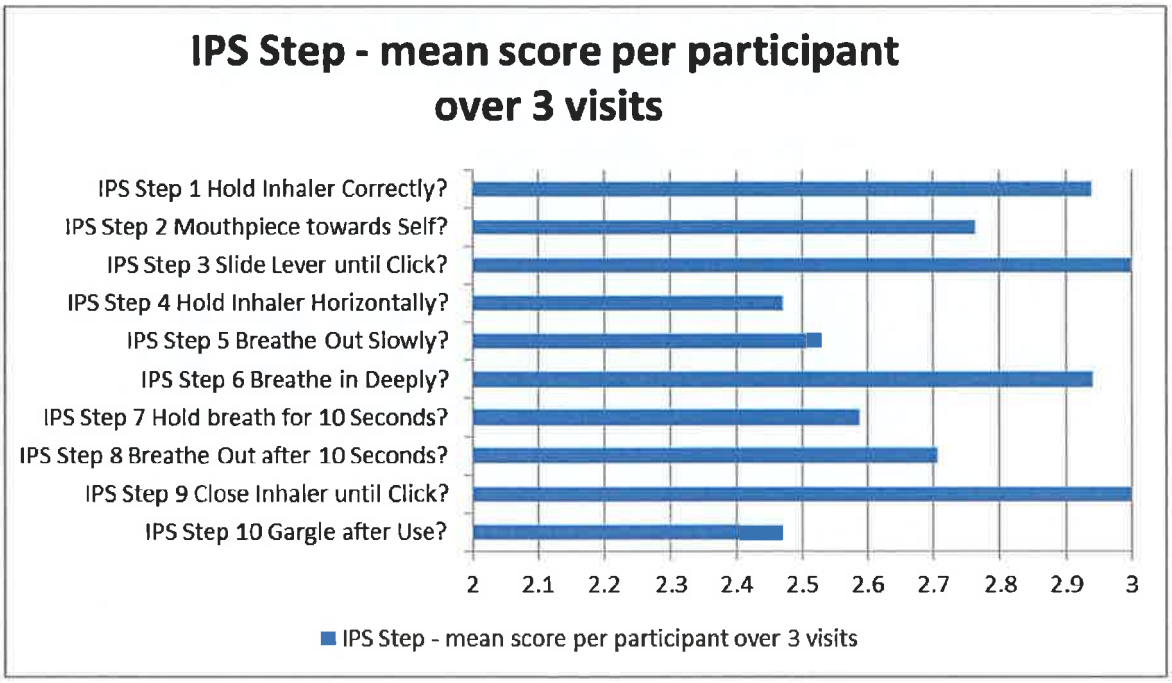


Figure 10. IPS Step – mean score per participant over 3 visits.

Looking at the Standard Deviation measure for each score, Steps 10 and 4 showed the greatest variation in scores, followed by Steps 5, 7, 8 and 2.

Step 1 and Step 6 almost achieved perfect scoring across all visits.

Step 3 and Step 9 achieved perfect scoring (zero standard deviation) across all visits.

A short explanation of the results per step is now outlined.

IPS Question 1: Does the participant hold the outer casing of the inhaler in one hand, whilst pushing the thumb grip away, until a click is heard?

The data shows that only one participant had an issue with this step on visit 1; this was identified and corrected on visit 1. All other participants completed this step correctly on visit 1, and all participants completed this step correctly on visit 2 and the follow-up visit.

IPS Question 2: Does the participant hold the inhaler with mouthpiece towards himself?

The data shows that three participants had an issue with this step on visit 1; this was identified and corrected on visit 1.The three participants whose technique was corrected on visit 1, performed this step correctly on visit 2 and the follow-up visit. All other participants completed this step correctly on visit 1, visit 2 and the follow-up visit, except for participant number 2, who performed this step incorrectly on the follow-up visit.

IPS Question 3: Does the participant slide lever away until it clicks?

The data shows that no participants had an issue with this step on visit 1, visit 2 or the follow-up visit. All participants performed this step correctly on each visit.

IPS Question 4: Does the participant hold the inhaler in a horizontal position?

The data shows that six participants had an issue with this step on visit 1; this was identified and corrected on visit 1. Five of the participants whose technique was corrected on visit 1, subsequently performed this step correctly on visit 2 and the follow-up visit. The sixth participant performed the step correctly on visit 2, but not on the follow-up visit.

One other participant who performed the step correctly on visit 1, had an issue with this step on visit 2, but performed the step correctly on the follow-up visit.

IPS Question 5: Does the participant breathe out slowly and then put inhaler in front of mouth?

The data shows that four participants had an issue with this step on visit 1; this was identified and corrected on visit 1. Three of the participants whose technique was corrected on visit 1, subsequently performed this step correctly on visit 2 and the follow-up visit. The fourth participant also had a problem with this step on visit 2, but did perform the step correctly on the follow-up visit.

One participant who performed the step correctly on visit 1, had an issue with this step on visit 2, but performed the step correctly on the follow-up visit. One participant, who performed the step correctly on visit 1 and visit 2, subsequently performed the step incorrectly on the follow-up visit.

IPS Question 6: Does the participant place mouthpiece between lips and breathe in as deeply as possible?

The data shows that only one participant had an issue with this step on visit 1; this was identified and corrected on visit 1. All other participants completed this step correctly on visit 1, and all participants completed this step correctly on visit 2 and the follow-up visit.

IPS Question 7: Does the participant remove inhaler from mouth and hold breath for about 10 seconds?

The data shows that five participants had an issue with this step on visit 1; this was identified and corrected on visit 1. All five of the participants whose technique was corrected on visit 1, subsequently performed this step correctly on visit 2 and the

follow-up visit. Two participants, who performed the step correctly on visit 1 and visit 2, had an issue with this step on the follow-up visit.

IPS Question 8: After 10 seconds does the participant breathe out slowly?

The data shows that five participants had an issue with this step on visit 1; this was identified and corrected on visit 1. All five of the participants whose technique was corrected on visit 1, subsequently performed this step correctly on visit 2 and the follow-up visit. All other participants performed this step correctly on visit 1, visit 2, and the follow-up visit.

IPS Question 9: Does the participant close the inhaler by sliding thumb grip back towards himself as far as it will go until it clicks?

All participants completed this step correctly on visit 1, visit 2 and the follow-up visit.

IPS Question 10: Does the participant gargle throat after use?

The data shows that two participants had an issue with this step on visit 1; this was identified and corrected on visit 1. These two participants subsequently performed this step correctly on visit 2 and the follow-up visit. These participants had been on DISKUS inhaler for 5 years and 10 years respectively.

Two participants, who performed the step correctly on visit 1, had an issue with this step on visit 2, but performed the step correctly on the follow-up visit. These two participants were new to DISKUS inhaler. Two participants, who performed the step correctly on visit 1, had an issue with this step on visit 2 and the follow-up visit. These two participants were also new to DISKUS inhaler.

4.3.3 Detailed analysis of the total IPS scores per participant for Visit 1, Visit 2 and the Follow-Up visit.

Having looked at the scoring for each question individually, the following tables summarise the total scores per participant for all ten questions on their IPS, as completed on each of visit 1, visit 2 and the follow-up visit. As each question scores 0 for incorrect performance and 1 for correct performance, the maximum score per completed IPS per participant visit is 10.

On visit 1, participant scores ranged from 4 to 10, with 67% scoring 9 or 10. The scores are summarised in Table 9.

Table 9. Visit 1 – Distribution of Total IPS Scores per Participant

Total Score per Participant per IPS	Frequency	Percent	Valid Percent	Cumulative Percent
4.00	1	4.8	4.8	4.8
5.00	1	4.8	4.8	9.5
6.00	2	9.5	9.5	19.0
7.00	2	9.5	9.5	28.6
8.00	1	4.8	4.8	33.3
9.00	1	4.8	4.8	38.1
10.00	13	61.9	61.9	100.0
Total	21	100.0	100.0	

On visit 2, participant scores ranged from 8 to 10, with 94% scoring 9 or 10. The scores are summarised in Table 10 below.

Table 10. Visit 2 – Distribution of Total IPS Scores per Participant

Total Score per Participant per IPS		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	8.00	1	4.8	5.6	5.6
	9.00	6	28.6	33.3	38.9
	10.00	11	52.4	61.1	100.0
	Total	18	85.7	100.0	
Missing	System	3	14.3		
Total		21	100.0		

On the follow-up visit, participant scores ranged from 7 to 10, with 89% scoring 9 or 10. The scores are summarised in Table 11 below.

Table 11. Follow up Visit – Distribution of Total IPS Scores per Participant

Total Score per Participant per IPS		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	7.00	1	4.8	5.6	5.6
	8.00	1	4.8	5.6	11.1
	9.00	5	23.8	27.8	38.9
	10.00	11	52.4	61.1	100.0
	Total	18	85.7	100.0	
Missing	System	3	14.3		
Total		21	100.0		

Overall the data shows an improvement in the total scores per participant from visit 1 to visit 2, and that this improvement is almost fully maintained on the follow-up visit. The improvement in visit 2 scores is 10% relative to visit 1 while the improvement in the follow-up visit scores is 9% relative to Visit 1.

Seven (n=7) of the participants show an improvement in their scores compared to that recorded on visit 1; five (n=5) of these participants had been on DISKUS inhaler for between 5 and 10 years; one (n=1) was on DISKUS inhaler for 3 months, while one (n=1) Participant was new to DISKUS inhaler.

Five (n=5) of the participants show a minor dis-improvement in their follow-up visit score relative to visit 1; one (n=1) of these participants had been on DISKUS inhaler for 5 years, while the other four (n=4) participants were new to DISKUS inhaler.

Five (n=5) participants maintained a perfect score on visit 1and the follow-up visit, although two (n=2) of this group did have a slight dis-improvement on visit 2. Both of these participants were new to DISKUS inhaler.

Statistically, the results show that the IPS data from visit 2 and the follow-up visit has both a higher mean and a narrowing of the standard deviation relative to the visit 1 data. The minimum score achieved by any participant also increased significantly.

4.4 How does newness to DISKUS inhaler impact on Participant performance?

The IPS data was categorised to separate the participant pool into two groups; those using DISKUS inhaler for the first time, and those already using DISKUS inhaler. The data shows that 66% (n=14) of participants were new to DISKUS inhaler, while 34% (n=7) of the participants had previously been prescribed DISKUS inhaler.

An independent Samples T-Test was performed on the data using this categorisation split. As with the previous analysis of the total participant population, this analysis also shows an improvement in the mean scores per category from visit 1 to visit 2, and that this improvement is almost fully maintained on the follow-up visit.

Closer examination of the data shows that those participants who had been on DISKUS inhaler previously performed more poorly on visit 1 than those participants who were new to the DISKUS inhaler. However, their mean scores improved significantly on subsequent visits, as did the standard deviation for their category, as per Table 12 below.

Table 12. Statistical Summary of IPS Scores per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all enrolled participants)

	Previous DISKUS use?	N	Mean	Std. Deviation	Std. Error Mean
Visit 1	No Previous DISKUS use	11	9.8182	.60302	.18182
	Previous DISKUS use	10	7.4000	2.22111	.70238
Visit 2	No Previous DISKUS use	10	9.6000	.51640	.16330
	Previous DISKUS use	8	9.5000	.75593	.26726
Follow Up Visit	No Previous DISKUS use	10	9.5000	.70711	.22361
	Previous DISKUS use	8	9.3750	1.06066	.37500

Inferential statistics refer to the use of current information regarding a sample of subjects in order to make assumptions about the population at large. A t-test is the most-widely used test in statistics. The purpose of the test is to determine if a difference exists between the means of two groups. The Independent Samples t- test compares the mean scores of two groups on a given variable.

In this study the total IPS score per visit for each of two groups was compared. Table 13 provides the test statistic (t value), the degrees of freedom and other values helpful for determining confidence intervals. A key statistic is the p-value, listed in the "Sig (2-tailed)" column. A p-value less than .05 indicates that there is a significant difference between the means of the two groups. A p-value greater than .05 indicates that the difference in means of the two groups is not statistically significant.

The results obtained in this study indicate that the statistical difference in the means in the two groups that exists on visit 1 is eliminated on visits 2 and 3 i.e. while both groups are significantly different at the outset, both groups do become statistically similar on subsequent visits.

The Independent Samples Test results for equality of variances and equality of means, as presented in Table 13, confirm the improvement in results.

Table 13. Independent Samples Test - Statistical Summary of IPS Scores per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all enrolled participants)

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Visit 1	Equal variances assumed	20.794	.000	3.481	19	.003	2.41818	.69474	.96408	3.87229
	Equal variances not assumed			3.333	10.205	.007	2.41818	.72553	.80600	4.03036
Visit 2	Equal variances assumed	1.540	.233	.333	16	.743	.10000	.30000	-.53597	.73597
	Equal variances not assumed			.319	11.911	.755	.10000	.31320	-.58297	.78297
Follow Up Visit	Equal variances assumed	.600	.450	.300	16	.768	.12500	.41716	-.75934	1.00934
	Equal variances not assumed			.286	11.711	.780	.12500	.43661	-.82889	1.07889

A second analysis of the data to exclude participants who did not complete all three IPS visits reconfirms the results. The data, as presented in Table 14, now shows an even greater improvement in performance for the "previous DISKUS use" group on subsequent visits when compared to their visit 1 results (base score 7.40 visit 1 for 10 participants vs. base score 6.43 for the 7 participants who completed all three IPS visits.

Table 14. Statistical Summary of IPS Scores per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all completed participants)

	Previous DISKUS use?	N	Mean	Std. Deviation	Std. Error Mean
Visit 1	No Previous DISKUS use	10	9.8000	.63246	.20000
	Previous DISKUS use	7	6.4286	1.90238	.71903
Visit 2	No Previous DISKUS use	10	9.6000	.51640	.16330
	Previous DISKUS use	7	9.4286	.78680	.29738
Follow Up Visit	No Previous DISKUS use	10	9.5000	.70711	.22361
	Previous DISKUS use	7	9.4286	1.13389	.42857

The Independent Samples Test results for equality of variances and equality of means, as presented in Table 15, again confirms the improvement in results.

Table 15. Independent Samples Test - Statistical Summary of IPS Scores per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all completed participants)

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Visit 1	Equal variances assumed	5.315	.036	5.266	15	.000	3.37143	.64020	2.00688	4.73597
	Equal variances not assumed			4.517	6.937	.003	3.37143	.74633	1.60337	5.13949
Visit 2	Equal variances assumed	2.243	.155	.545	15	.594	.17143	.31463	-.49919	.84205
	Equal variances not assumed			.505	9.583	.625	.17143	.33927	-.58899	.93184
Follow Up Visit	Equal variances assumed	.732	.406	.161	15	.875	.07143	.44470	-.87642	1.01928
	Equal variances not assumed			.148	9.254	.886	.07143	.48340	-1.01753	1.16039

The results indicate that repeated education improves IPS scores over time for those that need technique corrections, and that this improvement is well retained.

The data also suggests that participants who have been on DISKUS inhaler for longer are more in need of re-education compared to their more recently prescribed peers.

There is a gap of 3 months between visit 1 and visit 2, during which participants received monthly education; there is also a gap of 3 months between visit 2 and the follow-up visit, during which participants received zero monthly education. The results for each group drop slightly between visit 2 and the follow-up visit. For the

group with previous DISKUS use, this shows in the standard deviation; for the new to DISKUS group, it shows in a slight dis-improvement in both the mean score and the standard deviation of the scores.

4.5 Peak Flow

A Baseline Peak flow reading was taken for each participant on their initial visit for this trial. Three subsequent readings were taken on their visits at the end of month 1, month 2 and month 3. A fifth reading was taken 3 months later as part of a final participant follow-up visit.

Nineteen (n=19) of the participants completed all visits for PEFR readings. Two (n=2) of the participants only had one PEFR reading available, from their initial visit. Table 16 summarises the mean and standard deviation readings for the peak flow measurements of the participants, as recorded during the study.

Table 16. Statistical Summary of Peak Flow Readings for all enrolled participants

	All 5 PEFRS available?	N	Mean	Std. Deviation	Std. Error Mean
Peak Expiratory Flow Rate Month 0	No	2	375.00	7.071	5.000
	Yes	19	476.05	132.943	30.499
Peak Expiratory Flow Rate Month 1	No				
	Yes	19	482.37	116.098	26.635
Peak Expiratory Flow Rate Month 2	No				
	Yes	19	482.63	120.823	27.719
Peak Expiratory Flow Rate Month 3	No				
	Yes	19	469.63	128.838	29.557
Peak Expiratory Flow Rate Month 6	No				
	Yes	19	493.16	136.943	31.417

The data for the overall completing group indicates that the average readings for the group increased slightly from Month 0 to Month 6 (approx. 3.5%). It is ironic to note that the two participants who dropped out had by far the worst PEFR readings (average of 375 and individually 370 & 380 respectively).

The PEFR information was further analysed to assess the impact of newness to the DISKUS inhaler. The data is split between those new to the DISKUS inhaler and those who were already on the DISKUS inhaler. Table 17 summarises the mean and standard deviation readings for the peak flow measurements of the participants, as recorded during the study.

Table 17. Statistical Summary of Peak Flow Readings per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all completed participants)

	Previous DISKUS use?	N	Mean	Std. Deviation	Std. Error Mean
Peak Expiratory Flow Rate Month 0	No Previous DISKUS use	10	470.50	103.667	32.783
	Previous DISKUS use	9	482.22	166.116	55.372
Peak Expiratory Flow Rate Month 1	No Previous DISKUS use	10	493.50	97.070	30.696
	Previous DISKUS use	9	470.00	139.284	46.428
Peak Expiratory Flow Rate Month 2	No Previous DISKUS use	10	500.00	99.219	31.376
	Previous DISKUS use	9	463.33	144.827	48.276
Peak Expiratory Flow Rate Month 3	No Previous DISKUS use	10	503.30	87.496	27.669
	Previous DISKUS use	9	432.22	160.451	53.484
Peak Expiratory Flow Rate Month 6	No Previous DISKUS use	10	519.50	139.452	44.099
	Previous DISKUS use	9	463.89	135.964	45.321

The data indicates that those newer to DISKUS inhaler show improvements in their mean PEFR data. There is an increase of 10.4% in the average PEFR reading for this group from Month 0 Month 6. What is perhaps unexpected is that the group with previous DISKUS experience show a 3.8% drop in the average PEFR reading from Month 0 to Month 6.

The standard deviation scores for both groups generally improved except for a spike in Month 3 for the previous DISKUS use group, and in month 6 for the new to DISKUS group.

Table 18. Independent Samples Test - Statistical Summary of IPS Scores per visit, for new to DISKUS Group and Group with no Previous DISKUS experience (all completed participants)

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Peak Expiratory Flow Rate Month 0	Equal variances assumed	1.256	.278	-.187	17	.854	-11.722	62.790	-144.197	120.752
	Equal variances not assumed			-.182	13.155	.858	-11.722	64.349	-150.573	127.129
Peak Expiratory Flow Rate Month 1	Equal variances assumed	.163	.692	.430	17	.672	23.500	54.593	-91.682	138.682
	Equal variances not assumed			.422	14.124	.679	23.500	55.658	-95.776	142.776
Peak Expiratory Flow Rate Month 2	Equal variances assumed	1.546	.231	.650	17	.525	36.667	56.427	-82.385	155.718
	Equal variances not assumed			.637	13.970	.535	36.667	57.576	-86.846	160.180
Peak Expiratory Flow Rate Month 3	Equal variances assumed	2.963	.103	1.217	17	.240	71.078	58.423	-52.184	194.339
	Equal variances not assumed			1.180	12.086	.261	71.078	60.217	-60.020	202.176
Peak Expiratory Flow Rate Month 6	Equal variances assumed	.279	.604	.878	17	.392	55.611	63.325	-77.992	189.214
	Equal variances not assumed			.879	16.874	.392	55.611	63.235	-77.880	189.102

4.6 Participant Reported Behaviour

Each Participant completed a questionnaire containing a series of specific questions in relation to their condition, their confidence level with respect to their self-administration of their inhaler, and their adherence to prescribed frequency of use.

The participants were asked to answer the questionnaire on visit 1, visit 2 and on the follow-up visit. A total of 14 questions were presented: (1-6, 7a-7c, 8a-8d, 9 for Visits 1 & 2). The corresponding questions on the follow–up questionnaire are: 1-6, 13-a-c, 14a-d, 15).

The questionnaire used for the follow-up visit also contains some additional questions related to GP visits and steroid use in the 3 month period prior to their follow-up visit. The answers to these questions are already covered in Section 4.2.5.

A summary of the main findings and observations related to the 14 questions asked across all 3 visits now follows, and there is a more detailed analysis of the responses to these questions in Appendix 1.

4.6.1 Summary of Participant Reported Behaviour questions

A surprising number of participants did not have their inhalers with them on visit 1. While this improved significantly for visit 2, it had deteriorated again at the follow-up visit.

Only a maximum of three participants had ever been shown how to use their inhaler by the Pharmacist in the period preceding the completion of the questionnaire. An increasing number at each repeated questionnaire indicated they had been shown by a person other than their pharmacist. This may well have been the writer or someone in the medical-led study (the question was not clear enough to distinguish).

Only a maximum of two participants reported having any concerns about taking their inhaler. That said, the data shows that 6 participants reported that they had forgotten to take their inhaler on the day of visit 1. This number dropped to one on visit 2 and two on the follow-up visit. Various explanations were offered, such as

"forgot", "was rushing", and most worryingly, the fact that the canister was empty, which would be of concern.

Questions 7a-7c related to participant confidence in relation to using their inhaler correctly, taking it at the right time and using the prescribed number of puffs, and the effectiveness of their inhaler. The data shows increasing levels of agreement with the questions at each successive visit.

Questions 8a-8c focused on compliance related to carelessness and forgetfulness in use of their inhaler, and ceasing to use their inhaler. The data shows increasing levels of agreement with the questions at each successive visit, indicating higher levels of compliance at successive visits.

Question 8d indicates that on occasions, participants felt well enough to reduce their number of puffs.

Question 9 related to the participant confidence in the use of their inhaler – again the data shows that participants became more confident at each successive visit relative to their original visit.

In summary then, the Patient Reported Behaviour data is all trending positive where one would hope to see such trends emerging.

4.7 Summary

The Inhaler Proficiency Schedule data from visit 1 shows that participants who were previous DISKUS users were consistently taking their inhaler incorrectly. Education brought this group in line with newly educated, new-to-DISKUS participants. Subsequent visit data shows that repeated education improves technique, and that this improvement is sustained over the 6 month period of participation.

The Patient Reported Behaviour data from visit 1 shows that patients assumed they were taking their inhaler correctly. The PRB data changed on subsequent visits as the impact of the repeated education increased their understanding of past and current behaviour. In addition, the Patient Reported Behaviour data shows that patient adherence and compliance levels increase, as a result of the education.

Chapter 5 Discussion of Findings

5.0 Introduction

The purpose of this study was to explore the impact of a nurse led education programme in promoting compliance with inhaler use in patients with asthma and to consider the implications of the findings on the role and function of nurses.

This work was completed in the fulfilment of a Masters in Science in Nursing (Research). This placed limits on the size and scale of the study. In this chapter, the results obtained from the twenty one participants will be discussed in relation to the available published literature, and within the context of the aims and objectives of the study, and under the following headings:

- Demographics,
- Inhaler Education,
- Education and Compliance,
- Education and Confidence levels,
- Peak Flow.

5.1 Demographic Information

Twenty one (n=21) asthmatic participants enrolled in the study, comprising ten (n=10) men and eleven (n=11) women, with a mean age of 41years ± 14 years. 81% of participants (n=17) had at least one asthma exacerbation in the year prior to entering the study. The number of reported exacerbations in the prior year ranged from one to ten incidents.

These observations are in keeping with existing literature findings that asthma imposes limitations on all asthmatics, regardless of the severity of their disease. The INHALE Report (2008), notes that in Ireland, respiratory disease is the most common reason for people to visit their G.P. Approximately 25,000 A/E visits per

annum are asthma-related and there are 6,000 to 7,000 asthma-related admissions to Irish hospitals every year (Asthma Society 2007).

Seven (n=7) of the participants identified themselves as smokers, either current or past. This represents 33% of the participants who attended visit 1. This percentage is actually higher than the national average in Ireland, which in June 2010 was reported to be 23.6% (NTCO 2010). It is also higher than the findings of Chaudhuri *et al.* (2003), and Thomson and Spears (2005), who report that in most developed countries the prevalence of active smoking in adults with asthma is between 20% and 25%.

The percentage of smokers in this study is higher than the national average, but the sample size is very small, and the identified smokers were not all active at the time of entering the study. It is noted that smoking was an excluding criteria for the medical-led study, so to participate all participants who still smoked were asked and encouraged to give up smoking. All participants expressed their need and want to give up smoking, and participating in the study provided them with the necessary encouragement to finally stop smoking.

It is important to note that smoking does reduce the efficacy of inhaled corticosteroids (Kroon 2007). When comparing current smokers with asthma smokers and never-smokers with asthma, several studies have reported that current smokers have more severe asthma symptoms, accelerated decline in lung function, reduced response to corticosteroids, an increase in hospitalisations and increased mortality following near fatal asthma attack (Eisner *et al.*2001; Chaudhuri *et al.* 2003; Thomson and Spears, 2005; Stapleton *et al.* 2011).

5.2 Inhaler Education in Asthma

Inhaler education is a vital area of service provision and is fundamental to successful asthma control. NAEPP (2010), states that asthma self-management education is essential to provide participants with the skills necessary to control

their asthma and to improve their outcomes. This education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement. In the writer's study, inhaler education was repeated at every visit and good inhaler technique commended. GINA states that education should be an integral part of all interactions between the participant and all health care professionals.

The trigger for this research was a small unpublished pilot study in which the writer was involved. Twenty in-patients, who were using a DISKUS inhaler to which an acoustic device was attached, were enrolled. The purpose of the acoustic device was to record the participants' technique in taking their inhaler. This study showed significant and multiple errors in inhaler technique.

For the purpose of this study the writer focused upon the impact of a nursing education intervention on inhaler technique. Twenty one (n=21) asthmatic participants enrolled in the study to be educated in inhaler technique using a DISKUS inhaler. The typical method to evaluate inhaler technique is by assigning a score on the number of steps performed correctly out of the total number of possible steps (van Beerendonk *et al.* 1998). For this study the ten point Inhaler Proficiency Schedule (IPS) was used to score participant technique.

It is noted that 52% (n=11) of the participants had not previously been on DISKUS inhaler. 48% (n=10) of the participants had previously been prescribed DISKUS inhaler.

Participants were educated and assessed over a 6 month period. Education was imparted at month 0, at months 1 & 2 and again at month 3. IPS assessment took place at month 0 (IPS visit 1), again after a period of 3 months (IPS visit 2), and finally three months later the participants were assessed again (the follow-up IPS visit).

The results obtained in this study indicate that education eliminates the statistical difference in the means in the two groups i.e. while both groups are significantly different at the outset, both groups do become statistically similar on subsequent visits, through education in inhaler technique. The Independent Samples Test results for equality of variances and equality of means, as previously presented in Table 13, confirm the improvement in results.

There is a gap of three months between IPS visit 1 and IPS visit 2, during which participants received monthly education; there is also a gap of three months between IPS visit 2 and the IPS follow-up visit, during which time participants received no education at all. The results for each group drop slightly between IPS visit 2 and the IPS follow-up visit. For the group with previous DISKUS use, this drop shows in the standard deviation; this highlights the need for repeated education as the variation in IPS scores is greater than IPS visit 1, implying that some participants maintained their education better than others. The IPS visit 1 data also suggests that participants who have been on DISKUS inhaler for longer are more in need of re-education compared to their more recently prescribed peers.

For the new to DISKUS group, the drop in IPS scores from IPS visit 2 to the IPS follow-up visit shows in a slight dis-improvement in both the mean score and in an increase in the standard deviation of the scores. As the changes were very slight this could indicate that the newly prescribed to DISKUS participants have taken more enthusiastically to the training associated with their new medication, or have not had any time during which to develop poor habits in technique that have become ingrained and therefore difficult to rectify.

As not all 21 participants were able to attend all visits, the following overview is based on the 17 participants who have three complete sets of IPS data, gathered over a period of six months.

5.2.1 Newly prescribed to the DISKUS inhaler

The participants who were newly prescribed a DISKUS inhaler were first taught inhaler technique and then scored using the ten point IPS after their education. As expected these participants scored very well and so started from a high mean score of 9.8 out of a possible 10. This was expected as the participants had no preconceived ideas how to take this inhaler as the appearance of the inhaler was different from any inhaler the participant had used before, therefore the participant was receptive to education on this inhaler. This is consistent with Giraud *et al.* (2011), that education intervention results in good inhaler technique.

Only one participant had issues with two steps, relating to positioning the inhaler. Following the nurse education, this participant improved and maintained his improvement through subsequent assessments. This may be because the participant's starting knowledge of the DISKUS inhaler was low. This would be in keeping with literature which reports that immediately after face-to-face instruction participants are sometimes observed making mistakes in the use of their inhaler (Brocklebank and Ram, 2001).

The initial high mean score for this group of 9.8 on visit 1 was well maintained with 9.6 scored on visit 2 and 9.5 on the follow-up visit. The slight decline in mean scores could be an indicator that people with errors in technique require repeated and frequent education to eliminate the errors permanently. It could also reflect the three month gap in education between visit 2 and the follow-up visit.

5.2.2 Previously prescribed to the DISKUS inhaler

Seven participants who had previously been prescribed a DISKUS inhaler completed all visits and had their inhaler technique scored against the IPS on three occasions. The mean score that these participants received on visit 1 was 6.4 out of a possible 10, with some participants receiving a score as low as 4 out of 10. The

writer was shocked to find that 6 of the 7 participants who had previously been on a DISKUS inhaler had errors in their technique on visit 1.

The participants were then educated to correct their inhaler technique.

- Four of the participants improved their score to 10 by visit 2 and maintained this for the follow-up visit.
- Participant number 3 improved their score from a low of 5 on visit 1 to 9 on visit 2 and to a perfect score of 10 on the follow-up visit.
- Participant number 8 scored 7 on Visit 1and this improved to 9 on both visit 2 and the follow-up visit.

The initial low mean score for this group of 6.4 on visit 1 improved to 9.4 on visit 2 and was maintained at 9.4 on the follow-up visit.

It is apparent that repeated education brings the previous DISKUS users scores up to similar levels as the new to Diskus group, and that this education is retained during the three month gap between month three and month six.

5.2.3 Participant difficulties in using the DISKUS inhaler

All of the participants had been on some form of inhaler previously and so should have had some knowledge about the importance of inhaler technique. All 21 participants completed the IPS on Visit 1, but only 17 participants completed three sets of IPS data through the study.

On the ten point IPS there were some steps that all participants performed well on visit 1. There were also several steps that were performed incorrectly by some of the participants, increasing the risk of poor delivery of medication to the lungs.

The five steps with the lowest scores are now discussed in more detail, for the 17 participants with three sets of IPS scores.

Step 4 (hold the inhaler in a horizontal position)

The data shows that six participants had an issue with this step on visit 1; this step is important as if not performed correctly, the dry powder medication can fallk out of the device and the participant receives no medication. This error was identified and corrected on visit 1. Five of the participants whose technique was corrected on visit 1 subsequently performed this step correctly on visit 2 and the follow-up visit. The sixth participant performed the step correctly on visit 2, but not on the follow-up visit. Perhaps the participant did not grasp the full implication of incorrect positioning of the inhaler or maybe simply forgot. It is important to state that the participant had received education on inhaler technique monthly while participating in the medical- led study but this ended at month three. There was no education from month three to month six. These results demonstrate the importance of repeated education and reinforcement as stated in the NAEPP guidelines.

One other participant who performed this step correctly on visit 1, had an issue with this step on visit 2, but performed the step correctly on the follow-up visit. This finding shows that though participants appeared to know how to take their inhaler correctly, they could still perform steps incorrectly, so repeated education is of value to everyone.

A substantial number of errors were made with inhalation technique, as per the next three least well performed steps (i.e. steps 8, 7 and 5). This is similar to what Lavorini *et al.* (2008) report for most frequent device errors by asthma or COPD patients using the DISKUS inhaler. (See Table 19 below).

Table 19. Most frequent device errors by asthma or COPD patients using the DISKUS inhaler

Inhaler	1st most frequent error	2nd most frequent error	3rd most frequent error
Rotahaler®	No exhalation before inhalation	No breath hold	Incorrect inhaler position
Diskhaler®	No exhalation before inhalation	Incorrect dose metering	No breath hold
Turbuhaler®	No exhalation before inhalation	Incorrect inhaler position	No breath hold
Diskus®	No exhalation before inhalation	No breath hold	Incorrect dose metering
Cyclohaler®	No exhalation before inhalation	No breath hold	Incorrect inhaler position
Aerolizer®	No exhalation before inhalation	No breath hold	Incorrect dose metering
Ingelheim inhaler®*	No exhalation before inhalation		
Autohaler®*	No exhalation before inhalation	No breath hold	Incorrect mouthpiece positioning

*Only one study.

Step 8 (breathe out slowly after 10 seconds)

The data shows that five participants had an issue with this step on visit 1. This was identified and corrected. All five of these participants subsequently performed this step correctly on visit 2 and the follow-up visit. Participants were not aware that this was a step in inhaler technique; this was a step that was easy for the participant to learn and retain.

Step 7 (hold breath for 10 seconds)

As stated in the results chapter five participants did not hold their breath for the required length of time or at all on visit 1; following education all five performed this step correctly on visit 2 and the follow-up visit. Interestingly two participants, who performed the step correctly on visit 1 and visit 2, had an issue with this step on the follow-up visit. This was corrected and rectified. This lapse may be down to participants developing errors over time, which then become their "standard" behaviour; alternatively the participants may become more \ overly confident, and take shortcuts, for example speed up their technique. Whatever the reason, this observation also confirms the necessity of repeated education, and for the educator never to assume that the participant will not develop new errors in technique.

Step 5 (breathe out slowly)

Inhaled steroids may produce local side effects if inhaled particles are deposited in the mouth; these include a hoarse voice and the development of oral thrush as a

result of local immunosuppression (Bennett 2008). It is essential to empty the lungs so that medication can reach the respiratory tract and thus help prevent medication being deposited in the mouth, which leads to wastage of the medication (Kishore *et al.* 2008) and the side effects mentioned above.(Roland *et al.* 2004, Bennett 2008). Although this is a reported common error in the literature it was still surprising to see this occurring among the participants. It is quite difficult to take a deep breath in if you have not emptied your lungs in advance. However some participants find the act of emptying of emptying their lungs very difficult to do - perhaps this is because they are already focusing on the next step of breathing in deeply. Co-ordination of sequential tasks is obviously more difficult for some people.

Four participants had a problem with this step on visit 1; this was identified and corrected. Three of the participants whose technique was corrected on visit 1, subsequently performed this step correctly on visit 2 and the follow-up visit. The fourth participant also had a problem with this step on visit 2, but did perform the step correctly on the follow-up visit. Lavorini *et al.* (2008) reported that this was the most frequent error that their study encountered.

A study by van Beerendonk *et al.* (1998), evaluating inhaler use in 316 patients suffering from asthma or COPD found that 89% of the patients made at least one mistake in the inhalation technique. The most common skill error was "not continuing to inhale slowly after actuation of the inhaler" (69.6%). This was closely followed by "exhaling before the inhalation" (65.8%). The most frequent problems identified were failure to coordinate actuation with inhalation and to hold their breath after inhalation. According to Fink and Rubin (2005), between 28% and 68% of patients do not use their inhalers well enough to benefit from the prescribed medication. This is a staggering statistic.

Interestingly after education in this study, several participants complained that they could no longer taste the medication – this highlighted to the writer that their

technique had been very poor, as the sudden loss of "taste" was an incorrect signal to the participant that they were no longer getting the benefit of the medication.

Step 2 (hold the mouth piece towards yourself)

This step is ultimately self-correcting as the participant would eventually move the inhaler to the mouth, though this resulted in an element of fumbling. In effect, this step was skipped \ performed out of sequence, and interfered with correct performance of the ten step process.

Table 20 summarises the most frequent errors identified in this study related to breathing technique and inhaler positioning.

Table 20. Most frequent errors identified in this study.

1st most frequent error	2nd most frequent error	3rd most frequent error
Incorrect inhaler position	No breath hold and no slow exhalation after inhalation	No exhalation before inhalation

In this study, both the previously-prescribed DISKUS group and the new-to-DISKUS group have very similar scores on visit 2 and the follow up visit, which is indicative that inhaler technique education does improve and help maintain inhaler technique, and help to eliminate participant difficulties in using the inhaler.

5.2.4 Implication of IPS performance analysis for the Research Question

The Inhaler Proficiency Schedule findings answer the research question posed by this study, namely:

"What is the impact of a nurse led education programme in promoting compliance with inhaler use in patients with Asthma?"

The data shows that participants, who have been newly educated to the DISKUS, take the education on board and perform the ten step IPS well. Participants who have been on DISKUS for a period of time, perform much worse initially, but again take on board the education, and their scores improve to be in line with those participants just introduced to and trained in the use of the DISKUS device. The Patient Reported Behaviour data also indicates that training has either been poor or infrequent or both in the past, and the inference is that a result of this, long-term participants develop errors in technique over time.

One participant deviated from trend as a perfect score of 10 achieved on visit 1 dis-improved to an 8 on visit 2 and further dropped to 7 on the follow-up visit. Why did this occur? The writer was aware that this participant had received repeated education from the respiratory nurse specialist in the past; therefore the participant was able to take his inhaler correctly when being observed. However perhaps over time he became complacent within the study; indeed it could be just routine carelessness. Education should therefore be repeated as participants tend to forget inhaler technique and sometimes introduce errors over time (Rootmensen et *al.*2010). In addition, this type of result indicates that performance feedback is a key part of the education process. The writer believes that this is a good example of where regular objective numerical feedback could be of benefit to patients who do not seem to be able to control their asthma symptoms. More consistent technique should help to deliver medication more effectively.

The IPS results suggest that the inability of patients to correctly use their inhaler may be as a direct result of poor inhaler technique education. Education results in better inhalation technique and better asthma outcomes, but this education must be repeated regularly. It may be difficult to see how repeated inhaler technique education can affect compliance and adherence to inhaled medication regime, but as Takemura *et al.* (2010) report, repeated instruction affects the patient's belief and motivation to adhere to their medication regimen.

5.3 Education and Adherence \ Compliance

Adherence \ Compliance as stated in a previous chapter is defined as "the extent to which the patient's behaviour matches agreed recommendations from the prescriber" (NICE 2009). In this study the participants completed the Patient Reported Behaviour (PRB) questionnaire form. This tool asked a series of specific questions in relation to:

- their condition,
- their confidence level with respect to their self-administration of their inhaler, and
- their adherence to prescribed frequency of use.

This tool measured patient adherence - both intentional and unintentional non-adherence.

On visit 1, participants were questioned about their behaviour in the previous three months, using the Patient Reported Behaviour (PRB) Questionnaire. This showed that:

- 35% (n=6) of participants in this study did not take their inhaler at the correct time that day for a variety of reasons (*intentional/unintentional non-adherence*),
- 41% (n=7) did not use it as prescribed because they felt it was ineffective or uncertain that it was effective (*intentional non-adherence*),
- 65% (n=11) of participants reported that they had been careless about their inhaler some or most of the time (*intentional non-adherence*),
- 65% (n=11) of participants reported that they had forgotten to use their inhaler some of the time while 6% (n=1) reported that they had forgotten to use their inhaler most of the time (*unintentional non-adherence*),
- 41% (n=7) of participants either stopped using their inhaler or used it less than prescribed because they felt better! (*intentional non-adherence*).

This phenomenon of intentional and unintentional non-adherence is reported in previous studies (Rau, 2005, Takemura *et al.*2010). It is particularly worrying as the majority of these participants - fourteen (n=14) - all had exacerbations in the previous year, ranging from one (n =1) to ten (n=10) incidents.

In this study the mean years of asthma diagnosis for the participants was 17 years ± 12 years, with fourteen participants having been diagnosed for over 6 years. This study concurs with W.H.O. (2003) who state that adherence to medication regimens is often suboptimal when patients are on long-term pharmacotherapy using repeat prescriptions.

On visit 2, there was a vast improvement in participant reported behaviour, per the PRB data; 94% of participants took their inhaler at the correct time as compared to 65% on visit 1; 88% of participants believed their inhaler to be effective as compared to 59% on visit 1. Whereas 65% of participants were careless about using their inhaler some of the time or all of the time as per visit 1, this has been turned on its head and now 65% of participants are never careless about using their inhaler. Although participants still forgot to take their inhaler, this memory lapse was reduced from 71% on visit 1 to 65% on visit 2. 5% of participants sometimes stopped using their inhaler because they felt better, and incredibly not one participant used his inhaler less than prescribed because he felt better.

On the follow-up visit these improvements were well-maintained. 88% of participants still took their inhaler at the correct time; 88% still believed their inhaler was effective. 71% of participants are now never careless about using their inhaler; again while participants sometimes forgot to use their inhaler this was further reduced from 65% to 47%. In other words, the percentage of participants who never forget to take their inhaler has increased from 29% on visit 1, to 35% on visit 2 and now 53% on the follow-up visit. Only 12% of participants sometimes stopped using their inhaler because they felt better and 88% of participants never stopped using their inhaler because they felt better. Finally 18% sometimes used

their inhaler less than prescribed because they felt better and 82% never used it less than prescribed. This could be because the participants gained more insight into the benefits of a "preventer" inhaler and therefore continued using it, understanding that it would continue to keep them well. Previously they would have assumed that they do not need medication when they are well. One participant reported that they had not linked the terminology of "preventer" with the action that the medication was designed to prevent an asthma event from occurring. Figure 11 below summarises the responses of the patient pool to questions to measure non-compliance, both intentional and un-intentional. The data was gathered across three visits, and the trends show significant improvements in compliance levels from the first visit.

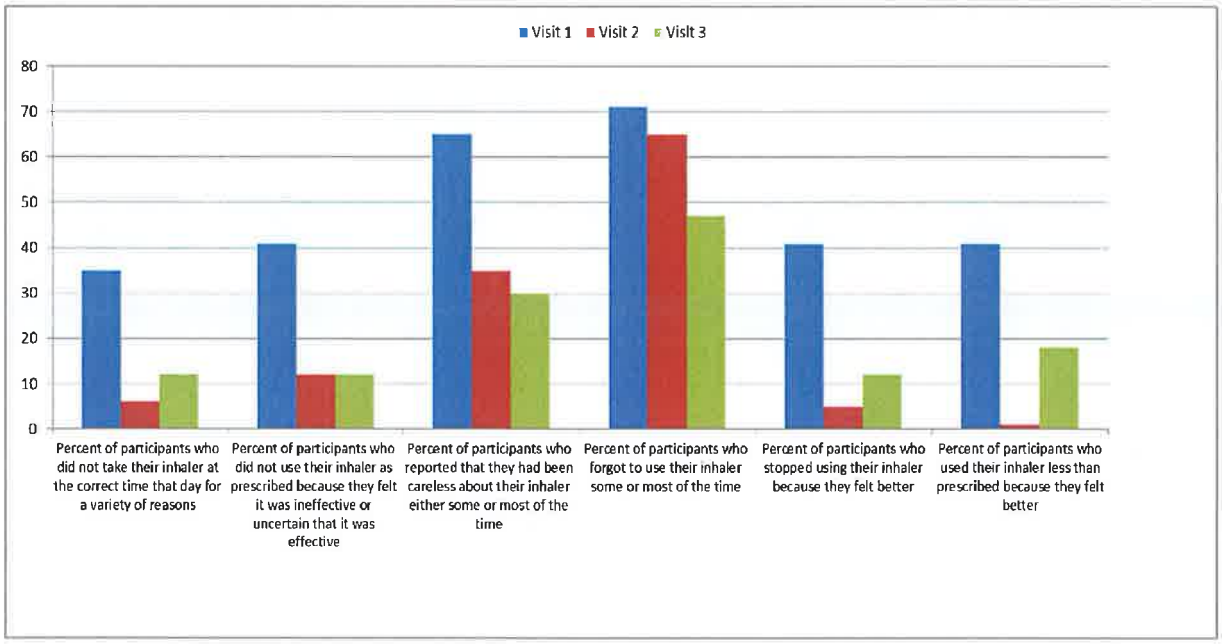


Figure 11. Overview of responses to questions to measure non-compliance, both intentional and un-intentional.

These results confirm the research question that a nurse led education programme can promote compliance with inhaler use in patients with asthma.

At the follow-up visit four participants reported that they needed to attend their GP for their asthma in the previous 3 months, on between 1 and 3 occasions. These four participants were prescribed steroids and all but one needed to increase their rescue medication usage. 82% of participants (n=14) had at least one asthma exacerbation in the year prior to entering the study. The number of reported exacerbations in the prior year ranged from one to ten incidents. This is difficult to discuss as there is not a comparable time frame to compare – in hindsight, a longer study could more accurately review patient history in more detail.

5.4 Education and Confidence

In 2010 Hickeys Pharmacy conducted a study involving over 1000 patients. This study found that only 35% of patients were taking their inhaler correctly; this finding gives cause for grave concern when combined with the fact that 91% of patients thought they were taking their inhaler correctly. These results are echoed by the writer's study. On visit one only 14% of participants took their inhaler correctly, however 64% of the participants believed they were using their inhaler correctly. Amazingly 88% of participants had identified no concerns or difficulties when taking their inhaler - as per their Patient Reported Behaviour Questionnaires.

It is important to highlight these issues as it must mean that most asthma patients think they are using their inhaler correctly and so they assume that general advice is not directed at them. This suggests that there is a large theory practice gap that needs to be narrowed and eliminated.

Some participants in the writer's study reported that they had been educated in the use of their inhalers in the past, although only three of these were educated by their pharmacist. This highlights an opportunity for pharmacists to become involved in inhaler education. There are some studies stating that pharmacists are ideally placed to educate people in inhaler technique (Odili and Okoribe 2010, Hickeys Pharmacy 2010). Following inhaler technique education, the participants became aware that

they had scored themselves incorrectly and expressed surprise that they were taking their inhaler incorrectly. As previously discussed the majority of errors were with breathing technique. Some participants were pleased that errors were found as they felt that this would lead to an improvement in their condition.

5.5 Peak Flow

A peak flow meter is a device that measures the maximum rate of air flow out of the lungs during forced expiration and is used for monitoring lung capacity of individuals with asthma (Merriam-Webster 2012). Peak expiratory flow rate (PEFR) is the maximum flow rate generated during a forceful exhalation (Medscape 2012).

The most frequent use of peak flow rate measurement is in home monitoring of asthma. The goal of the peak flow measurement is to help the patient recognise when their asthma may start to become uncontrolled. The goal for the patient is to stay within 80 per cent of their personal best peak flow measurement. When establishing a peak flow reading, the best of three measurements is recorded. In order to establish an understanding of their personal best peak flow, the patient takes peak flow measurements each day for two to three weeks. In this study the participants recorded their peak flow readings morning and evening for three months, in a peak flow diary.

The writer decided to see if there was any correlation between peak flow and inhaler technique. Peak flow measurements were recorded on visit month 0, 1, 2 and 3 of the medical-led study and were captured again 3 months later on the follow-up visit of the writer's study.

The data indicates that those newer to DISKUS inhaler show improvements in their mean PEFR data. There is an increase of 10.4% in the average PEFR reading for this group from Month 0 to Month 6. This shows that the DISKUS inhaler seems to be improving asthma outcomes for this group.

What is perhaps unexpected is that the group with previous DISKUS experience show a 3.8% drop in average PEFR readings from Month 0 to Month 6. This is an unexpected finding. Although the drop is small, as is the sample population, this raises concerns and these would need to be reassessed using a larger sample. The participants that have previous use with the DISKUS have improved their technique and compliance levels in the use of their inhaler, however the average peak flow for the group has dropped slightly over the 6 month period.

On the other hand, the readings for this group deteriorated by 10.4 % from Month 0 to month 3, but then showed an increase of 7.3% from Month 3 to Month 6. Looking at the data this way, is it possible that their medication is actually having an increased positive effect as time passes, i.e. the benefit of education on improving participant technique starts to kick-in for this group after a period of reinforcement. These are questions that would need more research to answer.

What is encouraging is that all readings over the period are well above the 80% group average of the participants starting scores on visit 0, with scores that range from 90% to 107% across the subsequent study visits.

5.6 Summary

The purpose of this study was to evaluate the effectiveness of a nurse led education programme to improve inhaler technique and promote compliance with inhaler use in patients with asthma. 21 asthmatic patients agreed to participate in this study, which involved a total of three visits over 6 a month period. A total of 17 completed all three visits, and the findings derived from both their IPS data and their Patient Reported Behaviour Questionnaire data were discussed.

Of the twenty one participants enrolled in the study, 81% had at least one asthma exacerbation in the year prior to entering the study. The number of reported exacerbations in the prior year ranged from one to ten incidents. These observations are in keeping with existing literature findings (The INHALE Report 2008).
This study has shown that inhaler technique education has improved participant inhaler technique, participant confidence levels in relation to self-administration of their inhaler and participant adherence to prescribed frequency of use.

Participants who were previous Diskus users performed poorly on their initial visit. This shows that experience of a device does not automatically guarantee good technique (Lavorini *et al.* (2008). The data also shows that once educated, the prior DISKUS users scores improved to similar levels as the new to Diskus group, and that this education is largely retained during the three month gap between month three and month six. This is consistent with Giraud *et al.* (2011), that education intervention results in good inhaler technique.

The data also shows that participants are capable of performing some steps incorrectly, even though they performed them correctly on a previous assessment. This would be in keeping with literature which reports that immediately after face-to-face instruction participants are sometimes observed making mistakes in the use of their inhaler (Brocklebank and Ram, 2001).

The four most common errors identified using the Inhaler Proficiency Schedule were: incorrect inhaler positioning, no exhalation before breathing in, no breath hold and no slow exhalation after breath hold. These results are reflected in the published literature (Lavorini *et al.* (2008).

The literature was plentiful in relation to non-adherence, both intentional and un-intentional. The Patient Reported Behaviour Questionnaire (PRB) was designed to capture intentional and un-intentional non-adherence. Each participant completed the PRB on each visit. All questions relating to non-adherence improved and again this is reflected in the literature. (Takemura *et al.* 2010).

The results showed that the participants were confident in taking their inhaler. This is interesting as participants assumed that they were taking their inhaler correctly and so did not think that education was targeted at them. However following inhaler technique education, the participants became aware that they had scored themselves incorrectly and expressed surprise that they were taking their inhaler incorrectly the participants were more receptive to education as a result. (Hickeys Pharmacy2010)

The Peak Flow data indicates that those newer to DISKUS inhaler show improvements in their mean PEFR data. There is an increase of 10.4% in the average PEFR reading for this group from Month 0 to Month 6. This shows that the DISKUS inhaler seems to be improving asthma outcomes for this group, and may simply reflect the fact that the switch to this medication is having a beneficial impact.

Peak flow readings for the prior Diskus users deteriorated by 10.4 % from Month 0 to month 3, but then showed an increase of 7.3% from Month 3 to Month 6. Looking at the data this way, is it possible that their medication is actually having an increased positive effect as time passes, i.e. the benefit of education on improving participant technique starts to kick-in for this group after a period of reinforcement. However, the sample size is small and the duration short - a longer

study with a larger sample size would be required to draw definitive conclusions from the peak flow data.

Chapter 6 Conclusions and Recommendations

6.0 Introduction

This chapter will present conclusions and recommendations based on the findings discussed in the previous chapter. The strengths and limitations of the study, the implications of the findings for nursing practice, patient care and the Health Service, will be considered. Recommendations for nursing practice, pharmacists, patients, and the Health Service will be made.

This chapter will also explain the process of dissemination for the findings and include the writer's reflection on the study.

6.1 Strengths of the Study

Before the study was started a comprehensive literature review was undertaken to determine how much knowledge was in the public domain, and to assess if there was a genuine need for the study.

The finding that education does improve inhaler technique is a strength corroborated by numerous studies (Lavorini *et al.* 2008; Restrepo *et al.* 2008).

Most studies just include a pre-test and post- test in their design. The decision to include a follow-up visit to check for retention of proficiency over time is a particular strength of this study, as this has not been performed in many other studies.

A real strength of this study is the relevance to clinical practice in that nursing education has been shown to have a positive impact. A linked strength is the health and social gain achieved by both the patient and the health service – education

improves patient well-being and therefore can reduce future patient demands on the system.

Having both the Patient Reported Behaviour questionnaire and the Inhaler Proficiency Schedule validated by a respiratory nurse specialist and a respiratory consultant added strength to the study design.

The study was conducted by an experienced research nurse who is trained in ICH GCP; this ensured the study was conducted ethically at all times.

This study was supervised by a highly qualified and experienced supervisor who ensured that the study was rigorous, so that the writer can be confident that all conclusions drawn are reliable.

6.2 Limitations of the Study

There were some limitations to the study which may impact negatively on the results. It was completed in the fulfilment of a Masters in Science (Research); this placed time constraints on data collection, and so limited the sample size. It also limited the follow-up period which would have benefited from being longer; it would have been very useful to assess whether or not correct inhaler technique and compliance were sustained over a longer time frame, and what impact continued \ discontinued education would have on the results, and on patient outcomes (e.g. exacerbations). Other limitations include the familiarity that grew between the researcher and the participants over time. Finally, a qualitative component to capture the anecdotal feedback of patients in relation to improvements in their condition would have been useful.

6.3 Dissemination of the Findings

The dissemination of research findings to and exchange of knowledge with appropriate audiences is an essential part of the research process and is crucial in bringing the research study to a successful conclusion (Flynn and Quinn, 2010).

The writer will seek to disseminate the findings at nursing conferences and indeed has already presented provisional findings at the Irish Research Nurses Network (IRNN) in Dublin in October 2011; a further presentation was given at the eighth Annual UK Clinical Research Facility Network (UKCRFN) Conference, which was held at Trinity College Dublin on the 5th and 6th of July 2012.

A poster was presented at the annual research day in the college to which the writer is affiliated (Royal College of Surgeons Ireland). The writer is also in the process of preparing a proposal to present a symposium at the fourth Annual International Association of Clinical Research Nurses (IACRN) Conference in Texas in October 2012.

The writer also plans to publish the research findings in peer reviewed nursing and respiratory journals. Oermann *et al.* (2010) state that nursing research is crucial for evidence-based practice, that the findings guide the improvement of new clinical practices and authenticate current practice.

6.4 Implications of the Findings

The purpose of this study was to explore the impact of a nurse led education programme in promoting compliance with inhaler use in patients with asthma and to consider the implications of the findings on the role and function of nurses. It transpires that there are also implications for patients, pharmacists and the Health Service, and these are now discussed below.

6.4.1 Implications for Nursing Practice

Nurses must be aware that they are accountable for their nursing practice and for working within their scope of practice (An Bord Altranais, 2000), and so nurses involved in educating patients must acquire the competencies and skills of an educator. This ensures that patients receive that best possible evidence-based care from a competent nurse. Nurses have a responsibility to the patients in their care and should be mindful that the standard and delivery of that care must meet the needs of the patient. Nurses must plan patient care and they also need to re-evaluate patient outcomes.

It has been shown in this study that nurse education does make a positive impact on inhaler technique and compliance, and as a result can lead to improved asthma outcomes. Numerous studies in different disease groups have shown that nurse case management, disease management and population-based management have all resulted in improved adherence/compliance to the recommended standard of care, with improved clinical and economic outcomes (Aubert *et al.* 1998; Sadur *et al.*1999).

It is vital that the results of this study are circulated to nurses working with patients using inhalers, in order to highlight that nurses have a valuable impact on inhaler use and compliance. Nurses are at the frontline of patient care, and so are well positioned to support the delivery of evidence-based research to the patient. This study shows that a minimal time input from nurses in educating patients on inhaler use impacts significantly on their asthma outcomes, including peak flow, confidence levels and their self-management of their asthma.

6.4.2 Implications for Nurse Education

This research has important implications for the education of nurses. One core competency of a nurse's role is education and training, where education of patients is advocated.

In the Lancet (2012) Editorial, "Science for action based nursing" reference is made to a report by the US Institute of Medicine (2010) which concluded by stating that nursing curricula should include evidence-based practice to allow nurses to translate research into better outcomes; however education alone is not enough to entrench it in daily practice and therefore nurse researchers must implement evidence-based practice within a healthcare system that values innovation (The Lancet 2012).

Because inhalers are used by many patients, and not just asthmatic patients, the writer believes that nurses should be at all times familiar with different inhaler techniques. Indeed the writer would campaign for inhaler technique education to be included in all undergraduate programmes. This education must be on-going, to ensure that all nursing staff continue to be competent in this area of practice.

6.4.3 Implications for Pharmacists

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is accountable for the effective regulation of pharmacy services in Ireland and works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies. Through the Pharmacy Ireland 2020 initiative, the PSI seeks to:

"...encourage, facilitate and support the greater involvement of pharmacists in the delivery of integrated, patient-centred, cost-effective health services, and the development of pharmacy services in Ireland in line with international evidence and best practice" (The Pharmaceutical Society of Ireland 2012).

The Irish Pharmacy Union (IPU) is the professional, representative organisation for community pharmacists in Ireland. Its stated mission is:

"...to promote the professional and economic interests of our members. Members of the IPU are committed to delivering a quality, accessible, personal and professional service that puts the patient first and has as its primary goal the optimisation of the health and well-being of society" (Irish Pharmacy Union 2012).

Patient education is a critical factor in the management and control of asthma; however education must extend beyond the nurse to include all health professionals working with the patient. All healthcare professionals have a duty of care to the patient.

In this research participants were asked if they had received inhaler technique education from anyone in the past. Twelve participants in the writer's study reported that they had been educated in the use of their inhalers in the past, although only three of these were educated by their pharmacist - the rest had been educated by nurses and doctors. This highlights an opportunity for pharmacists to become involved in inhaler education. Pharmacists are looking for ways to become more involved in the community and more proactive in public health. Inhaler technique education is an obvious way of achieving this. There are no losers in this scenario.

One method of reaching patients could be a through a sustained information campaign in Hospital waiting rooms, GP surgeries and Pharmacies, offering a free assessment of technique. A more valuable long-term option would be:

- the completion of an IPS or equivalent by the pharmacist every time a patient presents for a prescription renewal; this is usually monthly,
- the capture of history in relation to GP visits \ exacerbations since last renewal,
- the recording of a peak flow reading,
- the recording of this data centrally for analysis.

Using this approach, a very large volume of data could be collected for analysis in a short-period of time. In addition to the valuable insight this could provide, the increased interaction between patient and pharmacist should bring many of the benefits already identified in the writer's research e.g. greater adherence to taking of medication, improved technique and self-confidence, and importantly, the building of a bond between patient and Pharmacist.

The Asthma Society of Ireland could take a lead role in the development and promotion of this campaign with the Irish Pharmacy Union \ Pharmaceutical Society of Ireland.

6.4.4 Implications for Patients

As this study has shown, patient behaviour improves following a course of education, but it is important to stress that patients have an obligation to retain the skills they have learnt in order to maintain their own health to the best of their ability. GINA (2004) states the aim of asthma management is to control asthma symptoms rather than focus on treating exacerbations when they happen. NAEPP (2010), states that asthma self-management education is essential to provide patients with the skills necessary to control their asthma and to improve their outcomes. Education empowers people, but this education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement.

This study has shown that participants gained a greater understanding of their asthma through participation in the research. Their confidence levels in their ability to use their inhalers have correspondingly improved also. More often, they seem to take their inhalers at the correct time and in the correct dose - in other words they have become more adherent and compliant.

What is not recorded or measured in the data is the anecdotal feedback that each participant shared. The writer heard repeatedly that the participants didn't realise

that they had been taking their inhaler incorrectly. They didn't appreciate how well they could feel, even with a diagnosis of asthma. They didn't realise that they did not need a reliever medication every time they exerted themselves - and one man even stated that he could now cross a road without taking his inhaler!!

Another example: one lady had given up jogging and horse riding as a result of her asthma diagnosis. Following her education in inhaler technique she stated "my life has been transformed". She resumed all her activities and felt invigorated. This lady represents 5% of the participant population in this study – imagine what that would mean if replicated on a grand scale.

If patients can improve like this while being observed, it is incumbent upon them to ensure that they listen carefully and take on board the education that allows them to maintain this improvement. But it also suggests that the Health System can do more for patients with respect to education and management of symptoms.

6.4.5 Implications for the Health Service

In 2012, the Irish government will spend €13.3 Billion on running the Health Service. This represents a staggering 34% of the income (i.e. excluding borrowing) that the government expects to generate in the same period. At a time when the Government has committed to honouring the debts of the banking system, there is huge pressure to achieve a balanced annual budget as soon as possible. Ireland is currently experiencing a series of austerity budgets, which will probably continue to 2016.

Given the amount of money that the Health Service absorbs, it was inevitable that it could not escape cuts in funding, and this has already been seen in the budgets implemented in recent years. Funding for the Health Service has reduced from €14.8 Billion in 2009 to €13.3 Billion in 2012. Cuts in Health Services funding

usually lead to reductions in staff numbers or in the cutting of services, or a combination of the two.

In January 2012, the Economic & Social Research Institute (ESRI) published a report called "Delivery of Pharmaceuticals in Ireland – Getting a Bigger Bang for the Buck". This report was funded by the Health Service Executive. The report confirmed that Ireland spends more on pharmaceuticals per capita than any other OECD country (with the exception of the US, Canada and Greece). This amounted to €1.9 Billion in 2010, representing 12.9% of total public health expenditure.

This data shows that asthma is a hugely expensive condition for national Health Services, and this is not taking into account the indirect costs. At a time when funding is under such pressure, any changes in patient behaviour that improve patient well-being have the potential to deliver significant savings for the Health Service in general.

In an attempt to make savings the Health Information Quality Authority (HIQA) have introduced Health Technology Assessments (HTAs). This is research that gathers information about the clinical and cost-effectiveness of health technologies, that includes, drugs and medical devices. The aim of HTAs is to inform decision making within the publicly-funded healthcare system that will lead to maximum health gain and represent the most efficient use of the limited resources by the publically funded health care system in Ireland. The areas that HTAs focus on are:

- does the technology work?
- for whom does it work?
- what is the benefit to the individual?
- at what cost?
- how does it compare to the alternatives?

A HTA usually consists of two parts:

- A review of the available published and unpublished literature,
- An economic evaluation to see whether an intervention is cost-effective compared with the current situation (Health Information Quality Authority 2012).

The writer suggests that changes to new treatments should not be accepted without first assessing that current medications are being used correctly. Therefore in the case of asthmatic patients, the patient should have a period of assessment into their inhaler technique using the IPS (or equivalent) before changing their prescription to another inhaler or adding a different inhaler to their existing prescription.

6.5 Recommendations for Future Research

Although there have been numerous studies in the past on education in inhaler technique for both the educator and the patient, the fact remains that patients are consistently taking their inhalers incorrectly. Patients are reporting that they have not been taught how to use their inhaler by anyone, least of all a health care provider. Patients are also reporting that they believe that they are taking their inhaler correctly so assume that education drives are not targeted at them.

Further research needs to be done to explain this phenomenon. Crompton and Barnes (2006) note that some healthcare professionals have a 'blind spot' when faced with inhaler technique. To correctly teach inhaler use, healthcare professionals such as nurses, doctors and pharmacists should have adequate knowledge about inhaler use, as poor knowledge leads to poor patient asthma control. Further research into educating the educator in inhaler technique would therefore be of value.

There is scope for research into whether an Inhaler Proficiency Schedule would be of value, to assess inhaler technique at every point of contact that a patient has with a health professional i.e. doctors and nurses in primary care. For example, every time an inhaler is dispensed, should a patient be asked to demonstrate their inhaler technique to a pharmacist and to have their technique scored on the IPS.

As stated there have been numerous studies on inhaler technique, but not many that look at the impact of good inhaler technique on promoting compliance in inhaled medication regimens. This study did confirm that improved inhaler technique did improve compliance and adherence to inhaled medication but there would be value in repeating this study with a larger sample to see if the results could be replicated.

There are very few studies that incorporate a follow up visit and it would be of value if this piece of research could be replicated using a larger sample size to confirm the results of this study. In particular it would be important to see if continuing education leads to sustained improvements in technique, reduced exacerbations, fewer hospital \ GP visits, reduction in medication, improvement in peak flow.

The writer believes that a retrospective pre-test would also be of benefit in that it would provide a valuable reference to update patient perceptions prior to joining the study. Experience in this study has indicated that patients believe they are taking their inhaler correctly; a retrospective pre-test could provide valuable insight that would help to drive education and awareness campaigns.

This research has shown that nurses can contribute greatly to the body of knowledge available; their actions contribute significantly to patient wellbeing, patient understanding of their condition and treatments, and patient adherence to medication regimens. Nurses have a unique opportunity to engage patients to take responsibility for the management of their condition.

This study did not look at the potential financial benefits to the Health Service arising from patients who are better educated, who follow appropriate technique, and who take their medication as and when prescribed. So perhaps future longitudinal research with the opportunity to include cost benefit analysis might show that more formalised focus on patient education could bring significant financial benefits for the Health Service.

6.6 Reflections on the Study

Looking back on the last two years, I found the process of completing a Masters to be hugely challenging, at times exciting, and often isolating.

Because I work in research some parts of the process were much less challenging than others; for example the processes for ethics application, patient recruitment and data collection were all familiar to me, whereas statistics and findings were my Waterloo. I did learn about research methods and the importance of study design when exploring the research question. Over the years I have built up significant experience and confidence in my area of practice. My Masters experience has added to this. Through this research I have learned more about asthma management and the importance of educating the patient to their condition, and specifically the importance of good inhaler technique.

The process of doing one's own research is a completely different experience from working on someone else's. It is easy to ask a patient to participate in a research project associated with work, but it is difficult when you are a asking a patient to give up their time for your own research. It is important that the research is valid, and it is incumbent on the researcher to fully understand the commitment that the participant is making when agreeing to participate in the research. The participant is giving up their time in the hope of improving care for themselves and others, both now and in the future. The participant is trusting that no ill will befall them while taking part.

In this study I gained a new perspective into the interaction between patient and researcher. My level of interest and involvement with the patients increased, and I found myself looking forward to the next visits, and the additional information that would be collected to support my research. I would love to be able to share the results with them and to thank them for their participation and support.

At the end of a study I think every researcher wishes they had done some things differently. I would like to have incorporated a qualitative element to the study to capture some of the personal experiences that the participants shared with me. Because this is a Masters by research, at times the experience left me feeling isolated as I had no classmates to bounce things off, to learn from, or to offer \ share support with one another. On the other hand, my fellow research colleagues were a valuable support, that other students involved in taught Masters would not have available.

Recently, on a break in college, a class of at least 30 public health nurses came in for coffee. I could not help but think of the contact with patients that each nurse would have and what an opportunity it would be for me to educate these nurses in inhaler technique and so spread the knowledge and insight gained through my research experiences.

6.7 Conclusion

The purpose of this study was to explore the impact of a nurse led education programme in promoting compliance with inhaler use in patients with asthma and to consider the implications of the findings on the role and function of nurses. The findings of this study and the published literature indicate that there are significant implications for the role of nurses and it transpires for Patients, Pharmacists and the Health Service.

Incorrect inhaler usage is a significant problem in asthma management, resulting in poor control of asthma symptoms. The inability of patients to correctly use their inhaler may be as a direct result of poor inhaler technique education. Education apparently results in better inhalation technique, improved compliance and asthma outcomes, but this education must be repeated regularly.

The findings in this study show that inhaler education improves technique, promotes compliance and increase participant confidence levels in taking a DISKUS inhaler, and as a result asthma outcomes improve. The findings also show that participants thought that they were taking their inhaler correctly and so assumed that education drives were not targeted at them. This is a hurdle for health care providers to overcome.

Patient education is a critical factor in the management and control of asthma, however education must extend beyond the nurse to include all health professionals working with the patient. These findings provide an opportunity for patients, pharmacists and the Health Service to improve asthma care. This study indicated that participants were capable of learning and most importantly, maintaining correct inhaler technique, and as a result gain control over their asthma symptoms. It is imperative that patients are aware that they need to receive refresher education as bad habits can creep into their inhaler technique. Pharmacists are ideally placed to

monitor and educate inhaler users in inhaler technique on a monthly basis, when patients come to get their prescription filled.

The economic burden of asthma is very substantial and is one of the highest among chronic diseases. In the United States of America, approximately 5-7 billion dollars is wasted because of inhaler misuse per year. In this study 6 out of 7 participants who were previously on a DISKUS inhaler were misusing their inhaler. Any steps to reduce this wastage have to be embraced. It is noted that there are limitations to the generality of the results of this study; they do however provide some direction for future research in this area.

Nurses have a responsibility to continually question their practice and to provide the highest quality evidence-based care to their patients. Nursing research adds to a body of knowledge which contributes to and challenges evidence. By basing nursing practice on evidence-based knowledge, nurses will continue to develop professionally and help to define the unique role that nurse's play in healthcare provision.

In conclusion, this study demonstrates that repeated inhaler technique education seems to improve both intentional and unintentional non- adherence to inhaled medication regimens in asthma. Good adherence to inhaled medication may provide better clinical outcomes. In this admittedly small study, the patients newly prescribed to the DISKUS inhaler who were educated from the outset and regularly over 6 months, did show an improvement in their peak flow readings over the 6 month period that they participated in the study. Participants who had previously been prescribed the DISKUS showed significant improvements in technique. Their peak flow readings also increased from month 3 to month 6. All participants showed significant improvement in compliance and adherence.

Participant confidence levels in their inhaler technique were high from the beginning, though with hindsight the participants discovered this confidence was

misplaced, and they were able to correctly state their confidence levels on subsequent visits. Their confidence level in their inhaler increased through the study, and anecdotally they felt better.

Education programs such as this may also be effective because of the pre-requisite for participants to give up smoking, or the potential to encourage the participant as part of the education process to give up smoking. Applied on a larger scale, the additional benefits for both patient and Health Service could be enormous.

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Appendices

Appendix 1 Detailed analysis of the Patient Reported Behaviour Questionnaire

Each Participant completed a questionnaire containing a series of specific questions in relation to their condition, their confidence level with respect to their self-administration of their inhaler, and their adherence to prescribed frequency of use.

The Participants were asked to answer the questionnaire on Visit 1, Visit 2 and on the follow-up visit. A total of 14 questions were presented: (1-6, 7a-7c, 8a-8d, 9 for Visits 1 & 2). The corresponding questions on the follow–up Questionnaire are: 1-6, 13-a-c, 14a-d, 15).

This Appendix contains a summary of the responses to the above questions.

Questionnaire Q1: Do you have your inhaler with you today?
10 Participants did not have their inhaler with them on visit 1; 5 of these Participants were new to DISKUS inhaler; 5 of these Participants had been on DISKUS inhaler for between 5 and 10 years; one was on DISKUS inhaler for 3 months. All but one Participant had their inhaler with them on visit 2; this one Participant had been new to DISKUS inhaler as of Visit 1. 11 Participants did not have their inhaler with them on the follow-up visit.

Questionnaire Q2: Has your pharmacist shown you how to use your inhaler?
3 Participants on visit 1 reported that they had been shown how to use their inhaler by their pharmacist; the same 3 Participants on visit 2reported that they had been shown how to use their inhaler by their pharmacist; only one of these 3 Participants reported on their follow-up visit that they had been shown how to use their inhaler by their pharmacist.

Questionnaire Q3: Has any other person shown you how to use your inhaler?
11 Participants on visit 1 reported that they had been shown how to use their inhaler by a person other than their pharmacist; 15 Participants on visit 2 reported that they

had been shown how to use their inhaler by a person other than their pharmacist; 17 Participants reported on their follow-up visit that they had been shown how to use their inhaler by a person other than their pharmacist.

Questionnaire Q4: Have you any concerns / difficulties about taking your inhaler?

Only 2 Participants on visit 1 reported having any concerns \ difficulties with taking their inhaler; no Participants on visit 2 or the follow-up visit reported having any concerns \ difficulties with taking their inhaler.

Questionnaire Q5: Have you taken your inhaler today at the correct time?

6 Participants on visit 1 reported that they did not take their inhaler at the correct time; of these, 3 were new to the DISKUS inhaler. 1 participant on visit 2 reported that they did not take their inhaler at the correct time; this person was new to the DISKUS inhaler as of visit 1. 2 participants on the follow-up visit reported that they did not take their inhaler at the correct time; both of these people were new to the DISKUS inhaler as of visit 1.

Questionnaire Q6: If you did not take your inhaler today at the correct time, what was the reason for this?

6 participants on visit 1 reported that they did not take their inhaler at the correct time; their reasons for this are per the table below:

Participant ID	Explanation
1	Rushing
3	Did not take as attending clinic this day
8	Forgot
15	Canister Empty
18	Was on Ventolin PRN, so taken as needed
20	not on inhaler as of day of visit

1 participant on visit 2 reported that they did not take their inhaler at the correct time; their reasons for this are per the table below:

Participant ID	Explanation
18	Canister Empty

2 participants on the follow-up visit reported that they did not take their inhaler at the correct time; their reasons for this are per the table below:

Participant ID	Explanation
11	GP Visit
20	Forgot

Questionnaire Q7a: Please rate this statement: I use my inhaler correctly.
The scale has five possible answers: strongly agree / agree / uncertain / disagree / strongly disagree. The scale is scored from 1 to 5. The data shows that the mean score increases on visit 2 & the follow-up score from 3.71 to 4.56 to 4.68. At the same time the standard deviation decreases on visit 2 & the follow-up score from 1.145 to 0.511 to 0.478.

Questionnaire Q7b: Please rate this statement: I use my inhaler as prescribed (time of day and number of puffs).
The scale has five possible answers: strongly agree / agree / uncertain / disagree / strongly disagree. The scale is scored from 1 to 5. The data shows that the mean score increases on visit 2 & the follow-up score from 3.95 to 4.50 to 4.53. At the same time the standard deviation decreases on visit 2 & the follow-up score from 1.244 to 0.707 to 1.02.

Questionnaire Q7c: Please rate this statement: I believe my inhaler is effective.
The scale has five possible answers: strongly agree / agree / uncertain / disagree / strongly disagree. The scale is scored from 1 to 5. The data shows that the mean score increases on visit 2 & the follow-up score from 3.81 to 4.44 to 4.53. At the

same time the standard deviation decreases on visit 2 & the follow-up score from 1.289 to 0.705 to 0.841.

Questionnaire Q8a: During the last three months, have you been careless about using your inhaler?

The scale has three possible answers: most of the time / some of the time / none of the time. The scale is scored from 1 to 3. The data shows that the mean score decreases on visit 2 & the follow-up score from 1.90 to 1.33 to 1.37. At the same time the standard deviation decreases on visit 2 & the follow-up score from 0.768 to 0.485 to 0.597.

Questionnaire Q8b: During the last three months, have you ever forgotten to take your inhaler?

The scale has three possible answers: most of the time / some of the time / none of the time.

The scale is scored from 1 to 3. The data shows that the mean score decreases on visit 2 & the follow-up score from 1.76 to 1.61 to 1.53. At the same time the standard deviation decreases on visit 2 & the follow-up score from 0.539 to 0.502 to 0.612.

Questionnaire Q8c: During the last three months, have you ever stopped using your inhaler because you felt better?

The scale has three possible answers: most of the time / some of the time / none of the time

The scale is scored from 1 to 3. The data shows that the mean score decreases on visit 2 & the follow-up score from 1.62 to 1.06 to 1.11. At the same time the standard deviation decreases on visit 2 & the follow-up score from 0.805 to 0.236 to 0.315.

Questionnaire Q8d: During the last three months, have you ever used your inhaler less than your doctor prescribed because you felt better?

The scale has three possible answers: most of the time / some of the time / none of the time. The scale is scored from 1 to 3. The data shows that the mean score decreases on visit 2 & the follow-up score from 1.62 to 1.0 to 1.16. At the same time the standard deviation decreases on visit 2 & the follow-up score from 0.805 to 0.0 to 0.375.

Questionnaire Q9: Please rate your confidence level as to how well you use your inhaler.

The numeric scale runs from 1 to 10, where 1 is no confidence and 10 is complete confidence

The data shows that the mean score increases on visit 2 & the follow-up score from 6.90 to 8.78 to 8.89. At the same time the standard deviation decreases on visit 2 & the follow-up score from 2.071 to 1.309 to 1.10.

Appendix 2 Ethics Approval Letter

Ethics (Medical Research) Committee - [redacted] Hospital
Notification of ERC/IRB Approval

Chief Investigator: Ms. Elaine MacHale (Nursing/CRC-RCSI)

REC reference: 10/82

Protocol Title: The impact of a nurse education programme in promoting patient compliance of inhaler use in patients with asthma

Ethics Committee Meeting Date: 10th December 2010

Final Approval Date: 6th January 2011

From: Ethics (Medical Research) Committee - [redacted]

Document and Date	Documents Reviewed Date Reviewed	Approved
Application Form, V2, 20/12/10, unsigned	6/1/11	Yes
Research Proposal, no version number	6/1/11	Yes
Patient Information Leaflet & Consent Form V2, 20/12/10	6/1/11	Yes
Questionnaire, V1, 30/10/10	6/1/11	Yes
Inhaler Proficiency Schedule (IPS), V1, 30/10/10	6/1/11	Yes
CV: E. MacHale	6/1/11	Noted

[redacted]
ERC/IRB Chairperson
Approval # 1, dated 6th January 2011

Appendix 3 Inhaler Proficiency Schedule

Inhaler Proficiency Schedule (IPS)

Patient ID: _____

Date: _____

Visit No: _____

	YES	NO
Does the patient hold the outer casing of the inhaler in one hand, whilst pushing the thumb grip away, until a click is heard?		
Does the patient hold the inhaler with mouthpiece towards himself?		
Does the patient slide lever away until it clicks?		
Does the patient hold the inhaler in a horizontal position?		
Does the patient breath out slowly and then put inhaler in front of mouth?		
Does the patient place mouthpiece between lips and breathe in as deeply as possible?		
Does the patient remove inhaler from mouth and hold breath for about 10 seconds?		
After 10 seconds does the patient breathe out slowly?		
Does the patient close the inhaler by sliding thumb grip back towards himself as far as it will go until it clicks?		
Does the patient gargle throat after use?		

Appendix 4 Patient Reported Behaviour Questionnaire

Questionnaire

Patient ID: _____

Date: _____ **Visit No:**

_____

	YES	NO
Do you have your inhaler with you today?		
Has your pharmacist shown you how to use your inhaler?		
Has any other person shown you how to use your inhaler?		
Have you any concerns / difficulties about taking your inhaler?		
Have you taken your inhaler today at the correct time?		

6) If you did not take your inhaler today at the correct time, what was the reason for this?

_____

_____

7) Please rate the following statements:

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
I use my inhaler correctly	☐	☐	☐	☐	☐

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
I use my inhaler as prescribed (time of day and number of puffs)	☐	☐	☐	☐	☐

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
I believe my inhaler is effective	☐	☐	☐	☐	☐

8) During the last 3 months have you:

	Most of the time	Some of the time	None of the time
Been careless about using your inhaler?	☐	☐	☐

	Most of the time	Some of the time	None of the time
Ever forgotten to use your inhaler?	☐	☐	☐

	Most of the time	Some of the time	None of the time
Ever stopped using your inhaler because you felt better?	☐	☐	☐

	Most of the time	Some of the time	None of the time
Used you inhaler less than your Doctor prescribed because you felt better?	☐	☐	☐

9) Please rate your confidence level as to how well you use your inhaler.

No Confidence----------Complete Confidence

1 2 3 4 5 6 7 8 9 10

Appendix 5 Patient Information Leaflet & Consent Form

"The impact of a nurse education programme in promoting patient compliance of inhaler use in patients with Asthma"

Patient Information Leaflet

Principal Investigator's Name: Elaine Mac Hale.

Principal Investigator's Title:Research Nurse.

Telephone No. of Principal Investigator:

You are being invited to participate in a nursing study carried out at..... You are being asked to participate because you have been diagnosed with **Asthma**, and you are using, or about to start using, an **inhaler**. Before you decide whether or not you wish to take part, you should read the information provided below carefully. Take time to ask questions – do not feel rushed or under any obligation to make a hasty judgement. You should clearly understand the risks and benefits of participating in this study so that you can make a decision that is right for you – this process is known as Informed Consent. You are not obliged to take part in this study and failure to participate will have no effect on your future care.

You may change your mind at any time (before the start of the study or even after you have commenced the study) for whatever reason without having to justify your decision and without any negative impact on the care you will receive from the medical staff.

WHY IS THIS STUDY BEING DONE?

Asthma is a common medical condition in Ireland. Adult patients tend to have periods when their asthma is stable and periods when it worsens. When patients have severe persistent symptoms, guidelines recommend the use of a long-acting combination drug therapy in an inhaler. There is evidence that suggests that patients find it difficult to take this inhaler for a variety of reasons. The purpose of this nursing study is to discover if a nurse education programme is effective in promoting patient compliance of inhaler use in patients with asthma.

WHO IS ORGANISING AND FUNDING THIS STUDY?

This study is being carried out as part of a Masters Degree in nursing.

HOW WILL IT BE CARRIED OUT?

This study will start in January 2011. It is hoped to recruit 20 people in total from .... Hospital. These will be patients with asthma who are either using an inhaler at present or are about to start using one. Each patient will participate in the study for 3 months, with a follow-up visit 3 months after completion of the education programme.

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

The study will be explained to you in detail. If you then decide to take part in the study you will be asked to sign an informed consent document, giving your permission to join the study. You will receive a copy of this document and the patient information leaflet to take home with you. There will be 5 study visits. Visit 1 will be on the day that you agree to take part in the study; you will then be seen once a month for 3 months, and a final follow-up visit after another 3 months.

This study involves you demonstrating how you take your inhaler; if you make any errors these will be rectified. This study also involves a short interview where the nurse will ask you some questions about your condition, your medication and how confident you feel taking your inhaler. This will take about 20 minutes and will be done at a time and place that is convenient for you. About 20 patients from Beaumont Hospital will be invited to take part in this study.

WHAT ALTERNATIVE TREATMENTS ARE AVAILABLE TO ME?

Taking part in this research study is voluntary; you may choose not to take part; if you do take part you may also leave the study at any time. The alternative to taking part in the study would be the usual standard of care you would receive when you attend the hospital. Deciding not to participate or leaving the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

BENEFITS OF TAKING PART:

By taking part in the study you may benefit personally by improving your understanding of your condition and learning to use your inhaler more effectively.

RISKS OF TAKING PART:

There are no risks in taking part in this study.
This study has received approval from Beaumont Hospital Ethics Committee.

CONFIDENTIALITY ISSUES

All the information collected from you during the study will be kept confidential. During the study you will be identified using a unique study number and your initials. Any documents identifying you or containing your personal information will be locked in a cabinet. Only limited people involved in the study will have

access to this information. If the results of this study are published at any time in the future, your name will not appear in the publication.

IF YOU REQUIRE FURTHER INFORMATION:

If you have any questions about the study or if you wish to withdraw from the study you may do so without justifying your decision and your future treatment will not be affected.

FOR ADDITIONAL INFORMATION NOW OR ANY FUTURE TIME PLEASE CONTACT:

Elaine Mac Hale (Research Nurse), Ph.....

CONSENT FORM

I have read and understood the Patient Information Leaflet **YES ( ) NO ( )**

I have had the opportunity to ask questions and discuss the study **YES ( ) NO ( )**

I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care. **YES ( ) NO ( )**

I agree to take part in the study **YES ( ) NO ( )**

_____	_____	_____
Participant's Signature	Date	Participant's Name in print
_____	_____	_____
Witness Signature if required	Date	Witness Name in print
_____	_____	_____
Investigator's Signature	Date	Investigator's Name in print:

For additional information now or any future time please contact:

Elaine Mac Hale (Research Nurse),. Ph